MINDKIND
Final Report

Prepared for Wellcome Trust by Sage Bionetworks and Partners*

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* This report has been ratified by a vote of the MindKind Steering Committee

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  - Subsection 3. Youth Integration was authored by the project's professional youth advisors
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Section II presents project data against each of the four go/no go criteria pre-specified by Wellcome Trust.

In **Section III** MindKind's Professional Youth Advisors share their observations regarding the study arm outcomes, Go/No Go Criteria, and Requirements for a future GMHD.

Section IV summarises highlights from our collaborative Learnings about project processes.

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Highlights

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- Hearing the voice of youth participants, see quotes in sections **I.6.e, I.8.b,** and **I.8.g**.
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Acronyms and Abbreviations

AI: Active Ingredients

DUAG: Data Usability Advisory Group

GMHD: Global Mental Health Databank

IRB: Institutional Review Board, a type of ethics committee

PI: Principal Investigator or lead scientist

PYA: Professional Youth Advisor

Sage: Sage Bionetworks

Wellcome: Wellcome Trust

YPAG: Young People's Advisory Group

Executive Summary

Wellcome Trust (Wellcome) seeks to understand what interventions work for whom and why in order to prevent, treat, stop relapse, and manage ongoing difficulties with anxiety and depression in young people around the world. Because of the increasing ubiquity of smartphone use among young people worldwide, mobile devices, and associated research apps, are excellent candidates for remotely collecting longitudinal data about youth lived experience and its relationship to mental health.

To this end, Wellcome contracted with Sage Bionetworks (Sage) to prototype and test the feasibility of building a global mental health databank (GMHD) that houses rich, longitudinal, electronically-derived data from youth with a focus on the approaches, treatments, and interventions potentially relevant to anxiety or depression in 14-24 year olds.

Wellcome articulated a set of values to drive the two-year pilot project:
- Those banking their data shall have a high degree of involvement in decisions about the use of data and opportunities to act as citizen scientists.
- The data collected shall be made readily accessible to a wide range of researchers under conditions that protect the privacy of research participants to the extent agreed upon by those banking their data and consistent with any legal requirements.
- To support cutting-edge scientific research, there shall be sufficient ongoing engagement with those banking their data and with those who might analyse it to answer important research questions.

Sage Bionetworks, in collaboration with partners from the Centre for Mental Health Law & Policy, Indian Law Society, in India, Higher Health and Walter Sisulu University in South Africa, the Universities of Cambridge and Oxford in the UK, and the University of Washington in the United States, developed and executed the pilot study. We began by leveraging the team's extensive and diverse research experience to articulate a set of risk considerations to guide study design.

Conceptual risk considerations included:
- Digital extractivism: Given both the digital nature of this project and the disparate socioeconomic settings in which it will be conducted, data extractivism (including the perception of data extractivism) is a significant concern.
- Risk of individual solutionism/lack of recognition of social determinants of health: If not deliberately constructed, the GMHD may lead researchers (and participants) to incorrectly conclude that mental health problems of youth are solely explained by 'problems within the individual' and all the solutions are through 'changing the individual' or perhaps, at best, through 'the individual changing themselves'. Social determinants of health, including mental health, are significant contributors to illness.

Throughout the project we centre our efforts on the voices of young people, especially those with lived experience of mental health challenges, by grounding our work in a youth-researcher participatory research approach whereby we seek to involve youth stakeholders as equal partners. Each of the three sites hired a professional youth advisor (PYA) to join the study team, and we stood up multiple youth advisory teams for the project.

Each country-site hosted a Young People's Advisory Group (YPAG) who contributed members to a Global Youth Panel. These were supplemented by an ad hoc International Youth Panel convened by the University of Washington.

We also engaged a group of external researchers, the Data Usability Advisory Group (DUAG), to provide guidance about the direction and usability of the data and databank. This was comprised of researchers who might use a GMHD in their work.

To investigate the tension between privacy to participants and data availability to researchers, we began by exploring data collection and governance strategies with the pilot's youth and research advisors, identifying points of agreement and discordance in preference. We then further assessed the youth's preferences and acceptance of these models through a quantitative, app-based study arm and a discussion-focused qualitative study arm. We developed and released an enrollment website and mobile data collection study app for the quantitative study arm to test the feasibility of remote data collection. Within this framework, we implemented a randomized controlled trial of data governance strategies, as well as an independent assessment of engagement strategies. For the qualitative study arm we convened youth from India, South Africa, and the UK for two rounds of deliberative democracy sessions, exploring in-depth young people's feelings and experiences with sharing personal data, with a focus on mental health data, and their data governance preferences.

Questions that drove the MindKind Study include:
- How do we create a data governance structure that gives real voice to youth?
- How do we balance privacy concerns with open science approaches?
- How do we legally and ethically collect and hold data from around the world?
- How do we capture the right data for meaningful mental health research?
- How do we collect data that are rich in information about what helps young people and is not entirely focused on characteristics of people themselves?

The protocols and supporting research documentation were collaboratively developed and submitted for ethical and regulatory review in India, South Africa, the UK, and the US. Exacerbated by the COVID-19 pandemic, the ethics and regulatory approval process was complex and time consuming and would have been impossible without a central regulatory core and sites with local regulatory expertise working in concert with one another.

Recruitment
Quantitative study arm recruitment relied on direct outreach to youth (in person, peer recruitment, email, SMS), networking through local organisations, poster campaigns, and targeted social media advertisements (Instagram, Facebook). Social media advertisements were responsible for the recruitment of the vast majority of quantitative study arm participants: 80%, 55%, and 90% of those recruited in India, South Africa, and the UK, respectively.

Qualitative study arm recruitment focused on two cohorts: youth who were co-enrolled in the quantitative study arm and youth who were not (so-called "naïve" participants). Recruitment for naïve participants was swift for all sites, with sites reporting the effectiveness of emails to personal networks and partner organisations. These participants were also invited to share

the opportunity to participate in the sessions with their peers and in their social networks; this snowball strategy was also reported as effective. In contrast, the co-enrolled participants received an in-app pop-up notification with site specific links to join the study. Due to technical issues, some South African participants failed to receive this notification as expected and alternative outreach methods were employed.

Participants
In total, 3575 young people consented to participation in the quantitative study arm (1034 from India, 932 from South Africa, 1609 from the UK). The participant pool were mostly young people with lived experience with mental health challenges (88%, 67%, 91% in India, South Africa, and the UK, respectively) and identified as women (87%, 79%, 64% in India, South Africa, and the UK, respectively). More than half of participants in the UK were aged 16 and 17, however in India and South Africa the minimum age of participation was 18 (the local age of majority).

Of the 158 young people who participated in the qualitative study arm, approximately half were co-enrolled in the quantitative study arm. Approximately half of participants were aged 18-20 (or 16-20 in the UK), and half were aged 21-24. Other demographic characteristics were not tracked.

Outcomes
In the quantitative study arm, we found the proportion of participants contributing at least 50% of the protocol surveys was 3.8%, 5.3% and 10.1% in India, South Africa and the UK, respectively, greater than expected based on industry standards. Across all countries, we observed evidence of data loss (meaning data had been locally generated but were not fully captured in data upload processes), most acutely for participants from South Africa. For example, in India, South Africa and the UK, respectively, we observe 1.6%, 14% and 8% missingness of study topic annotation. Missingness appears to be particularly acute for larger files (e.g., from passive data recorders).

For the qualitative study arm, we hosted two-rounds of deliberative democracy sessions investigating the consensus data governance model(s) and concerns, hopes, and expectations of participants for a mental health databank. This process led to a set of more and less acceptable data governance options (deliberative outcomes) as well as major arguments and deeper thematic undercurrents of participants' reasoning (analytical outcomes), including the desire to *control the data* versus the feeling that one *can't control the data* and the (non-monetary) *costs* versus *benefits of data sharing*.

Notable results
There were a few notable surprises within the data collected. In the quantitative study arm, we measured the enrollment rates of various governance models, ranging from a traditional (researcher-friendly) model, which gives researchers more flexibility to how they access and use the data, to models that give youth more control over how their data are used and/or accessed. We expected that traditional models would be less acceptable to youth participants than those which provide them with more control over how their data were used or accessed. However, we found no statistically significant difference in enrollment rates across the models. While youth advisors, as well as participants across the quantitative and qualitative studies uniformly expressed preferences for these "youth informed" models, those

recruited to the quantitative study website were equally likely to enrol and engage in the study regardless of the governance model presented.

In a similar vein, we hypothesised that giving participants greater control over their study topics would lead to greater engagement with the app-based quantitative study. To do so, we randomised the enrolled participants to one of two engagement arms, the first of which allowed participants to choose their study topics ("active ingredients"), and the second of which assigned participants randomly to their topics. To our surprise, we observed that participants given a choice of study topics showed a statistically significantly *lower* engagement with the study than participants who were assigned fixed study topics.

Overall, we observed better than expected engagement with the app-based study than expected based on previous digital studies of mental health and with young participants in digital health research in general. We observed median days of retention of 2, 6, and 11 days for India, South Africa and the UK, respectively. In context, a previous meta-analysis of mHealth studies in the US observed a median number of days of retention of 2 days for this age group[1]. This is also generally more than that observed in the uncompensated mental health study, Start (median retention = 2 days), however it is substantially shorter than the mental health study, Brighten, in which participants were compensated for their participation (median retention = 26 days)[1]. While it is likely that compensation played a role in the differences between Brighten and our study, it is unclear why our retention rates were higher than other comparable uncompensated studies.

Feasibility against Go/No-Go Criteria
Wellcome prespecified a set of four Go/No-go criteria to assess the feasibility of a future GMHD around the topics of Governance and Ethics, Data Specification and Structure, Study Engagement, and Funding Sustainability.

Based on our results we assessed that the first two criteria indicated "Go" according to the pre-set criteria. For the Governance and Ethics criteria, we assessed that the governance structures for both data being banked and data being accessed showed high acceptability for data contributors (youth), as well as external researchers who reviewed the procedures for accessing the data.

For Data Specification and Structure, we assess that the data can be formulated, collected, stored, and described in a way that meets the needs of researchers across a range of requirements. Most importantly, the data, while stored in a general format, can easily be refactored or reshaped to meet a variety of complex analytical needs.

Our analysis of MindKind engagement data leads us to indicate "Not sure" relative to the pre-set no/no go engagement criteria. While we showed better than expected engagement in the app-based study on a relative scale (percentage of participants contributing at least 50% of protocol data over the course of the study), only one of the three jurisdictions met the go/no-go benchmark for absolute numbers of participants which had been pre-defined.

Finally, the assessment of feasibility of Funding Sustainability, indicated a "Stop" assessment. The preferences of youth in both the quantitative and qualitative study across

all jurisdictions were incompatible with a commercial business model which could be used to sustainably fund a future GMHD.

Data governance requirements

Based on our findings, we highlight a series of design requirements to guide specification development for the future GMHD. Four motifs are evidenced throughout the design requirements: issues of equity and global inequity, the tensions between the risks and benefits of data sharing, sources of bias in the data collected, and the role(s) of youth in the future GMHD. At the highest level, these motifs must be accounted for in any future global mental health planning, development, implementation, and analysis efforts.

Data governance specifications

The data governance requirement and data gathered from youth participants of the qualitative and quantitative study arms led us to a set of recommended specifications for the future GMHD. For example, youth agreed that data control boards/stewards should be paid for their work or, as a fallback, that data should be democratically controlled by data contributors. Youth also expressed a strong preference for data to be hosted on a server ("sandboxed") over data being available for download. Youth preferred that only mental health research be allowed on the data or, at most, health related topics. Notably, youth expressed concern about the role of money within the future global mental health databank: most did not readily support their data being used to generate a profit and were concerned about fees for data use being a barrier to equitable access. The complete set of specifications, developed directly from this study and attendant data governance requirements, can be considered a template for the initial design of the future global mental health databank.

Section I - Approach and Outcomes

1. Project design

MindKind is designed as a mixed-methods study to understand the feasibility of developing a global mental health database of digital data collected from young adults using smartphones. We hypothesise that young peoples' willingness to participate in digital research is influenced by their ability to be involved in how their data is collected, shared, and used. Our two-pronged approach paired a pilot (quantitative) smartphone-based study with a qualitative study to understand the participatory behaviours, concerns, and desires of young people with respect to mobile mental health research.

The quantitative sub-study piloted an app-based protocol, which queried participants' data governance preferences as well as the relative acceptability of governance models. The aim was to understand how study participants would prefer their data governed and accessed and how governance policies affect study participation. As a secondary aim, we tested two different engagement strategies to determine how short- and long-term engagement may be impacted by offering participants a choice of which mental health mediators--'active ingredients'-- they contribute to the databank. Here we define 'active ingredients' (AIs) as factors which have been shown to influence mental health[2]. In addition to collecting information on specific AIs, the quantitative substudy also gathered demographic information and mental health instruments in order to understand the willingness of participants to share information about their mental health on an ongoing basis. Participants interacted with a custom Android app to enable rapid and convenient data collection. Through this purpose-build app, we examined such factors as consent to enrol, the types of data contributed, and duration of data contribution.

The qualitative sub-study collected data from deliberative democracy sessions. Deliberative democracy is a method that joins communities in discussions of complex ethical issues by providing education to inform discussion and engaging participants in dialogue leading to iterative consensus building[3]. We applied this method to youth databank governance preferences with the aim to (1) identify the consensus data governance model(s) for an open yet privacy-preserving global mental health databank, from the perspective of multinational young people; and (2) understand the concerns, hopes, and expectations of multinational youth for such a databank with regards to the return of value to youth participants and youth participation in databank governance.

Both substudies were designed to inform our understanding of how to develop a global mental health databank for young people. The quantitative study asks questions about databank engagement, preferences, and acceptability within certain constraints. The qualitative study exposed participants to options for data management and storage that are not feasible to ask of participants in the quantitative study. Whereas the quantitative study collected data that can be compared across regions, the qualitative study put participants from different countries in direct dialogue with one another through multi-national deliberative sessions. This multinational session data offer insights into why certain preferential differences may arise in the quantitative app-mediated study. The qualitative study generated data that can be implemented in future iterations of the app-based (quantitative)

study by asking about an ideal scenario to aim for. The two substudies ran concurrently, and results from the two are designed to be compared in order to understand participants' ideals and their effect on participation relative to current research standards.

2. Project governance

Abstract

MindKind project governance was driven by the desire to foreground stakeholder voices, including those of both young people and researchers/users of the eventual databank. Additionally, we sought to create governance structures that supported clear and deliberate decision making while remaining agile enough to support the rapid timeline of the project. These guiding principles were implemented via specified project bodies — Project Teams to drive individual workstreams, a Steering Committee to drive us forward collectively, Young People's Advisory Groups (YPAGs) led by Professional Youth Advisors (PYAs) to centre the voice of young people with lived experience, and a Data Usability Advisory Group (DUAG) to ensure the interests of researchers were not overlooked. Our approach attempted to mitigate conceptual risks in addition to pragmatic risks identified at the start of the project.

At the project's mid-point, we performed a survey of project stakeholders which refined our approach to project governance for the remainder of the project. The results of the survey shaped improvements to intra-project communication which allowed us to function more effectively as a team. In this section, we explore key learnings with regard to intra-team communication and decision making and assess the success of our attempts to mitigate conceptual and pragmatic risks to project success.

Approach

The project governance structure for the MindKind Study was proposed by Sage Bionetworks and ratified by the GMHD partner organisations. Project governance was designed to be consensus-driven, guided by the principles highlighted in Box 2.a.1. These guiding principles were implemented via specified project bodies, meeting structures, and documentation requirements.

Box 2.a.1: Guiding principles for MindKind project governance

MindKind project governance:
- is transparent in structure
- allows for rapid, yet thoughtful, decision making
- captures a clear audit trail of decision making
- is participant driven and upholds scientific best practice
- encourages cohesion without forcing homogeneity

a. Project governance structure

The project had four project bodies, each with a standing meeting and documentation as detailed in Box 2.a.2.

Box 2.a.2: Overview of project governance

Project bodies	Standing meetings	Documentation
Project Teams	Project Team Lead Stand-up	Stand Up Minutes
Steering Committee	Steering Committee	Steering Committee Minutes
Young People's Advisory Groups (YPAG)	Professional Youth Advisor (PYA) Meeting	Youth Panel Summaries
Data Useability Advisors Group (DUAG)	DUAG Meeting	DUAG Feedback

Project Teams

Project Teams were the operational subunits of the project, responsible for driving project workstreams. Each Project Team was headed by a team lead, composed of representatives from each country and included at least one PYA. Project Team leads convened weekly at the Project Team Lead Stand-up Meeting to share brief progress updates, highlight barriers or blockers, and identify key interdependencies between teams that may impact progress. Project Team leads were responsible for including YPAs in decision making and distributing work to project team members. Project Team leads reported to the Steering Committee.

Steering Committee

All project team members were invited to attend bi-weekly Steering Committee meetings. The purpose of these meetings was twofold: to ensure the project was progressing to timeline and to ensure the project was progressing in line with the project vision (i.e., both participant-driven best practice science-driven, with the perspectives of youth at the forefront). Additionally, the Steering Committee was responsible for the commissioning of project teams, selection of Project Team leads, articulation of Project Team goals, and ensuring project team accountability. The Steering Committee's role also included removing and/or reducing barriers to project progress as identified by Project Teams.

Voting

Our project governance structure was intended to be consensus-driven and was constructed to allow for rapid yet thoughtful decision making. In instances where consensus could not be reached, we agreed upon a voting process. Voting members of the Steering Committee included the site leads (six votes), and PYAs (three votes). A vote could not be taken forward without a majority (2 of 3) of PYAs also voting in favour. Votes were to remain anonymous. Non-voting members were permitted to contribute as discussants.

Youth involvement

Our project governance structure explicitly codified the role of young people as central to all aspects of the project. All youth involved in this project have **either** self-attested to having a family member or friend or they themselves have experience with anxiety, depression, suicide/suicidality, or another mental health condition that impacts their life <u>and</u> they are committed to improving mental health treatment/interventions for young people through digital interventions **or** are they are youth who are committed to improve mental health

treatment/interventions for young people through digital interventions but may not have lived experience with mental health conditions.

Professional Youth Advisors (PYAs) were full-time, paid project staff, employed through their respective study sites. PYAs were selected based on their digital fluency, lived experience, age, strong writing and reading skills, and deep connection to their community; eligibility for the PYA role was not degree-dependent.

This project employed one PYA per study site (one PYA in India, one PYA in South Africa, and one PYA in the UK). Additionally, they served as Project Team liaisons and voting members of the Steering Committee. PYAs convened weekly in a meeting facilitated by a coordinating team at the University of Washington.

Each PYA was responsible for leading an in-country Young People's Advisory Group (YPAG). These groups each included 12-16 youth (the specific age range varied depending on local requirements related to the age of majority at each site). YPAG participants received an honorarium for their participation; in South Africa YPAG participants also received data to support their virtual involvement during the pandemic. YPAGs were critical to project development, direction, and decision making, and served as expert advisors to the project as a whole. Each in-country YPAG also contributed representatives to a global youth panel as described in Figure 2.a.1.

Figure 2.a.1: Youth Role in Project Governance

An ad hoc International Youth Panel was also convened by the University of Washington. Young people who participated in the International Youth Panel were not members of the in-country or global YPAGs.

Additionally, Wellcome employed a Lived Experience Consultant, who attended project meetings intermittently, including Professional Youth Advisor (PYA) Meetings. This individual was positioned within the project as a member of the Wellcome team and engaged with

Sage, PYAs, and members of the Steering Committee on processes pertaining to lived experience governance, communication, and engagement/outreach as an observer only.

Data Usability Advisory Group

The data usability advisors group (DUAG) was facilitated by the University of Washington and comprised of representatives from academic/medical institutions around the world. Through structured documentation, this group was tasked with providing feedback to the Steering Committee regarding data usability, research considerations, and ethics/regulatory issues.

b. Risks/Risk Management Strategies

At the start of the project, we identified several risks associated with the project that we sought to address through the project governance structure. Below we have included these risk management strategies as they were outlined in our original project governance plan:

Conceptual Risks

- *Risk of data extractivism:* Data extractivism is a form of exploitation whereby data are collected from communities, often without their input, and without the return of value meaningful to those communities yet with benefit to others. Given both the digital nature of this project and the disparate socioeconomic settings in which it will be conducted, data extractivism (including the perception of data extractivism) is a significant concern. Mitigation efforts will focus on promoting data justice through advisory boards (participant and community) that will guide data collection, access, and use decision making, as well as using qualitative and quantitative data derived from participants to ensure both the structure and function of the GMHD are consistent with participants' expectations for data sovereignty. The project will also focus on the direct return of value to participant communities through data access, data visualisation, and participant engagement in the assessment of findings.

- *Risk of individual solutionism/lack of recognition of social determinants of health:* If not deliberately constructed, the GMHD may lead researchers (and participants) to incorrectly conclude that mental health problems of youth are solely explained by 'problems within the individual' and all the solutions are through 'changing the individual' or perhaps, at best, through 'the individual changing themselves'. Social determinants of health, including mental health, are significant contributors to illness. Through qualitative interview of participants and translation of these insights into the study app/website, we will ensure that the program's technical platform captures not only the 'usual suspects' of social and economic determinants of health, but also factors participants themselves identify as influencing their mental health. For example, we may endeavour to identify coping styles/strategies that may be useful in keeping hope alive despite the significant challenges posed by social determinants of health.

Pragmatic Risks

- *Risk that data can not leave countries:* Data will be most easily usable by the broadest number of teams if data from multiple countries can be aggregated in a single location, such as a single cloud storage solution. If it turns out that there is no way to legally consent the data for aggregation in this way, Sage's platform does

support ways in which the data can be distributed across multiple storage locations, while metadata is still centralised, providing a way for researchers to query for what data is available. We expect data files that can not leave a particular country would be stored in the cloud providers' region-specific infrastructure (e.g. AWS regions in India, South Africa and UK), with download capabilities outside of each region disabled. Researchers needing to access the data would need to log into virtual machines in the appropriate AWS region, and be prohibited by the appropriate data use agreements and technical measures from exfiltrating the data from this location.

- *Risk that we can not obtain regulatory approval for a unified study protocol due to COVID-19 related government shut-downs:* Given the emphasis on developing this program as a unified program across multiple sites, we are motivated to address regulatory and ethical approvals using a stand-alone clinical protocol for the databank that is submitted in each country. Our initial investigations into this issue suggest that it is likely possible to receive regulatory approval for this study in all jurisdictions with only a two month review period. Thus, we are optimistic that this is possible. In the event that this is delayed, we have determined that both of the UK sites have existing IRB protocols that could be amended to initiate data collection on a more rapid timeframe.

- *Bureaucratic risks:* Bureaucratic systems at many partner organisations may slow project governance processes. For example, as much as the funding was made available, the ability to access the funding as and when it was required to keep the project going was often compromised at some sites, which hampered project progress.

c. Mid-project governance survey

Halfway through the project we conducted a mixed methods survey of project staff regarding the ongoing fit of project governance structures (Appendix I.2.c.1). Twenty-eight (28) project staff responded to the survey, 20 from one of the site teams (India, South Africa, or UK) and 8 not identifying as from a site team (Appendix I.2.c.2).

There was broad agreement among respondents that youth feedback was benefiting the project in meaningful ways. Most respondents felt they themselves were being heard and contributing meaningfully to the project (Figures 2.c.1 and 2.c.2), but some felt they were not incorporated in project decision making. Some respondents from the sites felt that they were sometimes treated more like "implementers" than "collaborators."
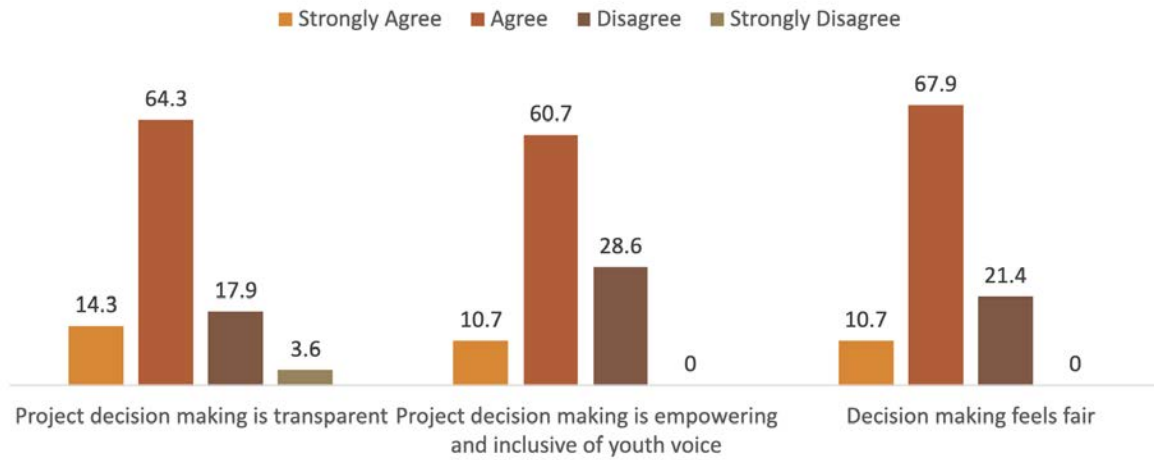
Figure 2.c.1: Satisfaction with project decision making
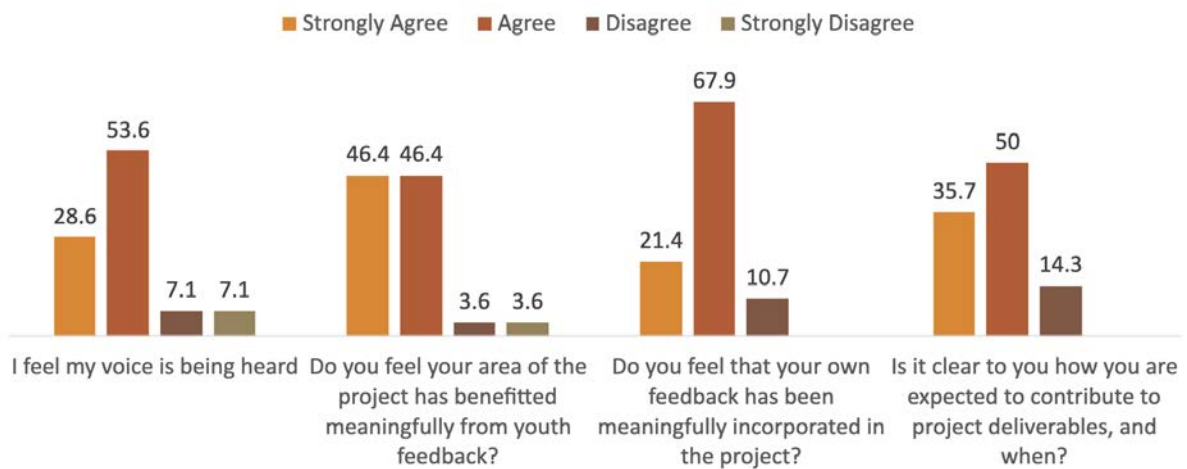
Figure 2.c.2: Whose voice is being heard?

We specifically asked about how to increase transparency to improve project-wide communication (Figure 2.c.3).
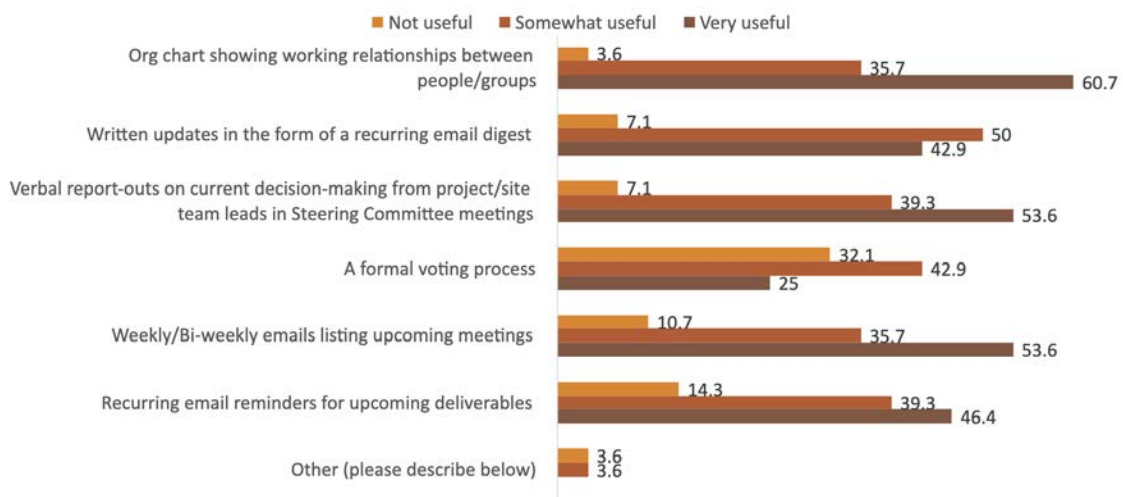
Figure 2.c.3: To increase transparency and understanding throughout the project, how useful would any of the following be?

We asked specifically about meeting content and cadence. Most respondents said that the space in which they share their thoughts is in project meetings. Also, each individual meeting received largely positive feedback. In the open responses, some people described some meetings as being too frequent or redundant.

In response to the survey findings the project's administrative core implemented two weekly email digests, which were distributed to all project members. First, a Monday morning "you are here" email was instituted to provide timely project updates and free up time at Steering Committee meetings for deliberation and discussion. This was complemented by a second weekly digest on Fridays which listed upcoming meetings and their purpose, and highlighted key deadlines and upcoming decision points. On a monthly basis, the Friday "next up" email included a status update on the progress of the project against its deliverables to Wellcome. Additional recommendations that resulted from the mid-project governance survey are documented in the executive summary (Appendix I.2.c.3).

Learnings

Intra-team Communications

- This project required sustained, active engagement in many meetings each week for all of our project leads, often at inconvenient times. Due to differing time-zones, regular Project Team meetings ran as late as 9:30pm for site members in India and as early as 6am in the US. It was easy to underestimate the impact that time zone differences would have on team morale at the project's launch which led us to inadequately assess the costs and benefits of our meeting-heavy communications strategy.
- With regard to the mid-project governance survey: While each individual meeting received largely positive feedback, some respondents described project meetings as being too frequent or too redundant. Meanwhile, themes from the open response portion of the survey highlighted a need for improved communication and greater transparency around how decisions were being made and who was responsible for making decisions. These results together informed our approach following the mid-project governance survey. We did not decrease the overall number of meetings being held. Instead, we focused our efforts on improving our non-meeting communication streams. Implementation of the twice-weekly email digests allowed us to spend more time actively collaborating in meetings and less time informing, which in turn allowed us to allocate more of our Steering Committee meeting time to decision making as a group. The Friday "up next" email digests also provided clarification about what to expect in upcoming meetings, which may have allowed team members to make more educated decisions about which meetings to attend, thus reducing meeting burden for some individuals.
- In order to facilitate cross-site learning amongst the recruiting sites, 'downstream meetings' were held once every three weeks. These meetings were utilised differently depending on the phase of the study. In this case, adding a meeting served to lessen the burden of work for individual sites. These meetings were able to be held at a time of day that was more convenient for attendees because neither the US-based teams (University of Washington, Sage) were required.

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<u>**Voting as a Tool for Team Decision Making**</u>

- We only used Steering Committee voting to ratify official policy documents (Authorship Policy and the Community Norms & Safeguarding Policy).
- In practice, our formal voting process was too cumbersome to use in most cases. Being a fully remote, multinational team meant that voting took place asynchronously via online forms. This approach was stymied when voting members were unable to respond in a timely manner. Our initial project governance plan also failed to provide criteria for determining when a vote should be required. As a result, some team members reported struggling with questions like:
  - What questions are big enough to deserve formal votes?
  - Which kinds of decisions should be made as a group?
  - How do we find out about decisions being made by other work streams without going to all of their meetings.
- Our formal voting process was introduced to PYAs as a key component of our project governance plan at the beginning of their involvement in the project, but was rarely initiated in practice. This presented as a conflict between our plan for decision-making vs. our standard work, and contributed to the perceived lack of transparency around decision-making reported by team members in the mid-project governance survey, as discussed in the previous section.
- In this system, PYAs held voting power, but many of their fully academically-situated peers did not. At times, we observed that PYAs were subjected to pressure from their peers to vote in support of the interests of others. The relative inexperience of PYAs in the politics and pressures of the academic world as compared to their fully academically-situated peers may have made them more vulnerable to influence and should be a key consideration when designing future project governance structures in which youth will be fully integrated.

Recommendations

<u>**Intra-team Communications**</u>

- Our mid-project governance survey helped refine our approach throughout the remainder of the project. However, this assessment was only initiated after signs of tension were already evident within the team. We recommend taking a more iterative approach to intra-project communications. For example, smaller-scale checks like the survey we deployed could be used on a more regular basis to ensure project governance is meeting the needs of team members while not so changeable as to be confusing.
- Given that time zone differences are likely to continue to pose challenges for global teams, we recommend that project teams commit upfront resources to crafting a communications strategy that includes asynchronous communication channels to supplement and support better meeting hygiene. We found weekly digests to be a useful strategy for achieving balance between meeting burden and asynchronous communication.
- Steering Committee meetings should be structured to facilitate as much active collaboration as possible. To this end, it is helpful to frame discussion of project deliverables in team meetings such that all team members not only get updated on past decisions but are able to contribute meaningfully to decisions that are yet to be

made. We recommend including a 10-minute slot for discussion of "next up" deliverables at the start of each Steering Committee meeting. This could be structured as "What we have done so far, where we are currently, and what do we need to do next". This would be especially useful for new members joining the consortium.

● To enable cross-learning, a separate meeting can be set up to facilitate inter-site interactions.

Voting as a Tool for Team Decision Making

● We recommend that future project teams consider including a formal voting process in their governance documentation, but acknowledge that voting may only be used for ratification of formal policy documents. Whether or not teams use a formal voting process or other methods for team decision making, the way that decisions are made and the individuals who have authority to make project decisions should be clearly enumerated in the project governance documentation. Standards for decision making should be reviewed and updated often enough to ensure that they are representative of a team's actual practices so as not to be misleading.

● If a formal voting process will be included in the project governance plan, criteria for determining when a vote is required should be included in the process outline.

● If PYAs or other citizen scientists are empowered to exercise their preferences through a voting system as a component of the project governance plan, care should be taken to safeguard against undue peer influence.

Risks/Risk Management Recommendations

● While all efforts must be made at the start of the project to ensure that partners are chosen that will be able to effectively utilise and monitor funding and other resources, should this become problematic, flexibility is required and other options must be found so that the project is completed timeously.

3. Youth Integration

Abstract

A professional youth advisor (PYA) from each of India, South Africa, and UK, made tremendous contributions to this project, but resource inequality, lack of role clarity, and rapid project timelines created challenges to PYAs' involvement. PYAs found themselves providing emotional support for their young people's advisory groups (YPAGs) in addition to supporting varied research functions within their own team. In this section, the PYAs describe how early project involvement, safeguarding protocols, and accountability for YPAG contributions can increase the climate of transparency and trust among youth stakeholders.

a. Professional Youth Advisors (PYAs)

Approach

Involving young people with lived experiences of mental health challenges has been central to the MindKind study. The team from the University of Washington provided ongoing support alongside a lived experience consultant from the Wellcome Trust. Young peoples' involvement in the MindKind study were operationalised at a country site level by Professional Youth Advisors (PYAs) who coordinated involvement with in-country youth panels, international panels, and the broader MindKind team.

We hired one PYA per country, into a paid full-time position at their local institution (Oxford University in the United Kingdom, Centre for Mental Health Law & Policy, ILS in India, and Higher Health in South Africa). Young people were eligible to be PYAs if they: were fluent in the use of digital communication approaches; had "lived experience" with one or more mental health conditions, defined as self-report of themselves, family, or friends having experience with anxiety, depression, suicide or suicidal ideation, or another mental health condition that impacted/impacts their life; were between 14-24 years of age; had strong writing and reading skills; and had a deep connection to their community. A specific degree or level of education was not required for this position. PYAs were full study team members and as such attended and presented at Steering Committee meetings and were voting members of the Steering Committee (1 vote per PYA). They organised and led bi-monthly youth advisory group meetings, selected topics for these sessions and recorded key findings in the study AirTable database, conducted capacity building activities with youth panel members, advocated for youth panel members at project team meetings, and reported back to youth panel members on key project decisions. They were largely seen as the "diplomats," providing connections between the youth advisory groups, the project team, and the Wellcome Trust.

This section reflects on the key learnings about PYA recruitment, involvement and support. The points below have been shaped by the team from University of Washington and the Professional Youth Advisors themselves, with support from the lived experience consultant from the Wellcome Trust. This section presents key learnings and recommendations developed by those directly delivering young peoples' involvement in MindKind. It is hoped that these recommendations would improve approaches to youth involvement in mental

health research as well as in complex international studies at the intersection of young peoples' mental health and data.

Learnings

Project Planning

Hiring Professional Youth Advisors (PYAs)

PYAs were hired after initial project proposals and infrastructure had been developed in the Sage-led consortium's application to the Wellcome Trust. Initial youth involvement methodologies had been developed by the MindKind consortium during the grant application process and, as PYAs were being hired and onboarded, an ad-hoc group of youth from across the globe were recruited, convened, and consulted on project activities to provide youth voices. This meant that there was a lack of continuity between initial youth involvement and that led by PYAs. Furthermore, this meant that PYAs were unable to use their expertise to shape the foundational thinking around youth involvement from the beginning of MindKind.

India Professional Youth Advisor

Swetha Ranganathan was hired as the Professional Youth Advisor for the India site (Centre for Mental Health Law & Policy, ILS). Prior to joining the Centre, she worked on developing a mental health advocacy toolkit for young people in India. Her previous experience of working with the youth, her lived experiences of mental health challenges, and a Masters degree in Psychology helped her represent the voices of young people. She is passionate about suicide prevention in young people and wants to work towards developing and providing accessible and affordable mental health services for them. Like the other two PYAs, the team from the University of Washington and a lived experience consultant from Wellcome provided ongoing support to her. She reported administratively and for local guidance directly to the India team leads.

South Africa Professional Youth Advisor

Refiloe Sibisi was hired as the youth lead for South Africa, serving both local research sites (Higher Health and the Walter Sisulu University). She was employed due to her previous work with youth in NGOs, experience in higher education (though she had not yet completed her degree) and lived experience of a mental health condition. She showed passion for improving youth mental health and for involving youth in all matters that affect them. She fitted the MindKind study criteria of involving young people with lived experiences of mental health challenges. The team from the University of Washington provided ongoing support alongside a lived experience consultant from the Wellcome Trust. She reported administratively and for local guidance directly to the South African team leads.

UK Professional Youth Advisor

Emily Bampton was hired as the Professional Youth advisor for the UK serving both local research sites (University of Oxford and University of Cambridge). She was employed due to her personal lived experience of mental health and passion for improving diversity in mental health patient and public involvement, with a particular focus on gender and ethnicity. As well as her strong administrative background and previous work with young people through Oxfordshire Apprenticeships. Like the other two PYAs, the team from the University of

Washington and a lived experience consultant from Wellcome provided ongoing support to her. She reported administratively and for local guidance directly to the UK team leads.

Ensuring a Point of Contact

PYAs felt that there could have been a better identified central point of contact and co-produced systems for queries related to youth involvement. Whilst many individuals formed the central youth involvement team, having someone with more responsibility for supporting and enabling involvement would have improved communication and connection between PYAs and the central organising team.

Recognising Plurality of PYAs

PYAs have a range of different interests and skill sets which could have been used positively in various parts of MindKind and to support different project teams and the wider consortium. While the PYAs worked extensively with the qualitative study team, their expertise could have been called upon more extensively in other project areas (for example, the quantitative study design and engagement approaches). These opportunities can enable the PYAs' personal and professional development through capacity building.

Project Policies to Ensure Proper Safeguarding

Some PYAs felt as though it was difficult to raise concerns about involvement, well-being, and other difficult issues due to them feeling more junior in comparison to other project members. In some instances, at the project level and at the site level, PYAs' concerns were not handled properly, meaning that some PYAs felt unable to properly advocate for themselves and each other in the context of the project. This led to challenges emerging which could have been prevented if user friendly communication and escalation processes were in place.

Management and Support

Empowering Support and Management

Some PYAs felt as though they were not receiving managerial and team support from their in-country team which hampered the progress of youth involvement in MindKind. PYAs outlined that managerial and support check-ins are opportunities for team members to connect and reflect beyond daily project tasks, and are key to identifying and acting upon any project challenges before they become more serious. Some PYAs outlined that all in-country project management should also be confident and comfortable with providing specialised support to PYAs and involvement practitioners as well as research staff.

Invisible Emotional Care

Working closely with their in-country youth panels, PYAs were often communicating with participants regularly across extended periods of time. As such, participants might share certain personal challenges they are experiencing as PYAs were often seen as trustworthy and good listeners. As such, PYAs often had to perform pastoral and emotional care which went beyond their immediate role remit, and sometimes required certain skills which they did not have.

Recommendations

Project Planning

Recruiting PYAs as Early as Possible

PYAs should be recruited as close to the confirmation of a project as possible to ensure that all points of a project timeline can be informed by youth insights and that there is a continuation of involvement from application to delivery phases. Furthermore, recruiting PYAs earlier would give them more say in decision-making and setting the involvement agenda on a project, enabling improvements in capacity, skillset, and experience.

Ensuring a Central Youth Integration Lead

While each PYA worked in a particular geographic context to deliver the MindKind study, an alternative model of management and operation could have been constructed. One option could be to have a central Youth Integration Lead on such projects to ensure consistency and communication with the central team leading the research consortium. This person would be responsible for onboarding, enabling, and supporting youth involvement as well as support with escalating any concerns held by PYAs about the project. This position would ideally be another young person with relevant experiences of building youth involvement infrastructure. Another option is to have the central team focused on integration of youth voices to hire all of the Professional Youth Advisors to ensure consistent central check-ins, concern raising process, as well as being integrated into site-teams. It was felt that the existing infrastructure was helpful but it would have been easier to reach out to someone whose sole role was to lead and support youth integration on the study.

Project Policies to Enable Proper Safeguarding

The project governance structure did not include a specific process for youth concern escalation. Commissioned organisations should provide clear safeguarding and escalation processes created with PYAs that allow the raising of concerns in a way that will be heard and responded to by appropriate project members. It is noted that having a weekly meeting with multiple members is not an appropriate place to raise concerns and also sometimes concerns are best made through anonymous mechanisms.

Management and Support

Ensure Regular Formal and Informal Touchpoints with PYAs

There should be touch points between PYAs, the central commissioned organisation, funders, and site-leads for regular formal and informal check-ins. To this end, the project's weekly formal Youth Advisory Team meetings ensured ongoing project support. Monthly informal PYA and Funder meetings were times where cross learning could take place and concerns could be raised. To supplement this, central commissioned teams should have the ability to impact and influence situations of concern within specific geographic sites. While this should have ideally been addressed as part of contracting, future teams must set up mechanisms to ensure supervision within site teams, setting up standards of conduct with youth engagement, having accountability check-ins with team leads/managers, and intervening when necessary to ensure that young people receive formal capacity building as well as emotional support when necessary.

PYAs should be provided with a suitable package of facilitation, listening, and psychological first aid training as a part of their on-boarding as well as having access to a capacity building fund through the project. The capacity building fund would fund external trainings that PYAs can take up to build their capacity on providing psychological first aid/pastoral support to YPAG members. One such package recommended by PYA was: *2-day Mental Health First Aid* training as well as group facilitation training, like *Groupwork Matters: How to Facilitate Groups More Effectively*.

Furthermore, it is important to open these opportunities (accessing trainings on providing psychological first aid) to youth panel members to help build their knowledge of well-being, resilience, and coping mechanisms. This would support their personal well-being and equip themselves with better coping skills/provide support to other panel members for any vicarious trauma they may come into contact with as part of the panel by listening to others' lived experiences.

b. YPAGs

Approach

One of the main mechanisms for youth involvement in the MindKind study was the Young People's Advisory Group (YPAG) or youth panel. Each in-country site had a YPAG which comprised a group of young people between the ages of 18-24 (India, SA) or 16-24 (UK); the specific age range of the YPAG depended on local requirements related to the age of majority.

The groups were comprised of 12-16 youth per country, and PYAs sought to ensure YPAG members represented diverse youth from their countries based on geographic region, race/ethnicity, gender, language, and lived experiences of mental health concerns. YPAG members were asked to attend bi-monthly meetings, generally held virtually, throughout the project period, to provide feedback on various aspects of the project and to assist with decision making on project activities. YPAG members received honorarium (in all three sites) and data (in South Africa) for their involvement in the project. YPAG members were also occasionally invited to participate in "extra" activities, such as manuscript writing, presentations, and membership on a Global Youth Advisory Panel (see below).

YPAGs had multiple points of contact with the study team. They helped shape data governance procedures, data usability expectations, and data collection approaches, as well as serving as co-authors amongst other points of involvement.

Learnings

YPAG Recruitment and Support

Enabling Diverse Insights in YPAGs

Professional Youth Advisors noted that it is important to recognise the need for a diverse range of viewpoints and experiences within the YPAGs. Such an approach must be intersectional and multi-dimensional, insofar that recruitment should take into consideration

the most prominent social structures of inclusion and exclusion within their context or YPAGs could become spaces which represent a tiny fraction of youth insights. Therefore, youth who may have derived different insights from their experiences of, for example, class, caste, and language, must have a place in the YPAG which should be closely considered during the recruitment phase. Recruiting a diverse membership for YPAGs requires more time in recruitment and enabling of linguistic diversity.

Supporting YPAGs through Capacity Building

While youth involvement becomes increasingly popular in mental health science and research, it is important to recognise that youth do not all have access to the skills to thrive during involvement. As such, it is the responsibility of power-holders to ensure that youth who are involved can build their skills and knowledge in relevant areas which can enable more meaningful involvement in a project. There exists a plethora of skill sets and expertise in the MindKind research team and it is important to support young people accessing such resources when they are needed. Whether this be by facilitating introductory sessions to different topics or by sharing chances to enhance involvement opportunities, it is integral to reciprocally build knowledge and skill sets with youth beyond them being contributors to a project. In the MindKind study, capacity building was definitely a positive feature and should be emphasised and emboldened. Capacity building sessions were supported by PYAs and members of the central team. Additional support, for example provision of letters of reference for youth involved in the project, were also needed and appreciated.

Emotional and Pastoral Support for YPAGs

Whilst one may assume that working with youth in this project simply means discussing facets of MindKind, Professional Youth Advisors highlighted the extra-role responsibilities required during the study. Some of these responsibilities related to providing emotional/pastoral support to youth who had, over time, developed a sense of familiarity, comfort, and trust with PYAs. As such, it is important to understand how youth can access emotional and pastoral support through their involvement. Within this, safeguarding and role boundaries should be considered, but should not be reason to dismiss the provision of this type of support. Whether through access to wellbeing apps, psychoeducation, or career support/coaching, YPAG members should be provided with ways of supporting themselves whilst demonstrating long-term involvement in the study.

Administrative and Financial Support for YPAGs

YPAG members were paid for their involvement depending on the time spent on the project. However, some members experienced difficulties with being paid – whether administrative or technological issues – which considerably delayed remuneration. Different geographic contexts may have popular payment infrastructure which requires some administrative and bureaucratic work to ensure youth are paid on time. In such a study with three geographic sites for youth to be paid, it is important to consider these challenges and develop potential solutions and back-up plans before the first payment for involvement is required.

YPAG Impact

Involving Youth from the Start

Integrating youth involvement is often seen as an afterthought in research projects, but in the MindKind study, youth involvement was sought throughout the delivery of the project.

However, on a project of such a scale it can be hard to develop continuity through youth involvement processes, most notably before in-country YPAGs were recruited when an ad-hoc panel of youth informed the initial project. Professional Youth Advisors noted that if there is a lack of continuity between earlier and later youth involvement infrastructure it can make decision-making less transparent and perceived as more prescriptive. Ideally, standard elements of youth involvement (e.g., having youth representation from the process of ideation) would have shaped the grant application through to project delivery. By ensuring continuity it will help transparency and highlight the power youth actually have and can expect in how their insights direct the MindKind study more widely.

Closing the Feedback Loop on Decision Making

Traditionally, youth involvement dynamics are comprised of a research team who extract insights and information from young people. However, it is absolutely integral to challenge these dynamics and infuse a sense of reciprocity and transparency into youth involvement activities. Through the MindKind study it was recognised that closing the feedback loop on decision making was essential to ensure youth knew how their insights were being used. On the project this involved regular communication about what insights had been incorporated and what hadn't. This helps youth to understand how their insights and knowledge are impacting a project and whether they shaped or did not shape decisions made. To support this feedback loop, MindKind tried to ensure that research teams provided feedback directly to the YPAGs as well as using a feedback mechanism through AirTable to communicate how insights were or were not being actioned.

YPAG Engagement

Confronting Digital Inequities

While online meetings and ways of working have become commonplace especially over the last three years, it is important to note that online spaces are not always suitable or accessible for youth involvement. There are three key learnings around how online-only work can perpetuate inequities. First and foremost, online meetings require a digital device able to connect to the internet which is not always accessible for youth around the world. Further, said devices often require stable internet connection which can be costly if it is not readily available. In one geographic site, youth did not all have ready access to the internet and required financial support to participate in online meetings. In this particular site, online meetings were supplemented with in-person meetings where most appropriate and also WhatsApp was used to facilitate asynchronous participation. Beyond cost, even if youth had an internet connection it was not necessarily stable. In some contexts there was regular 'load shedding', which aims to manage high demand for electrical power. Load shedding could lead to internet and power being cut in a particular area for an unspecified time, thus impacting access to the internet and therefore youth involvement. With a project spanning three diverse geographic contexts it is important to think about the benefits and drawbacks to online-only engagement and whether it makes most sense to facilitate a hybrid model of youth involvement.

Creating a Climate of Trust and Understanding

Even if a YPAG is perfectly structured, it is integral to ensure that the engagement approach and strategy is carefully considered. The approach to engagement within YPAGs helps to build a trusting and comfortable dynamic which can enable more meaningful youth insights.

Within the YPAGs it was noted that building long-lasting rapport with participants was hugely beneficial to ongoing involvement (Figure 3.b.1). Research systems are laden with power structures which means that care and consideration are required when communicating, especially in an involvement context.
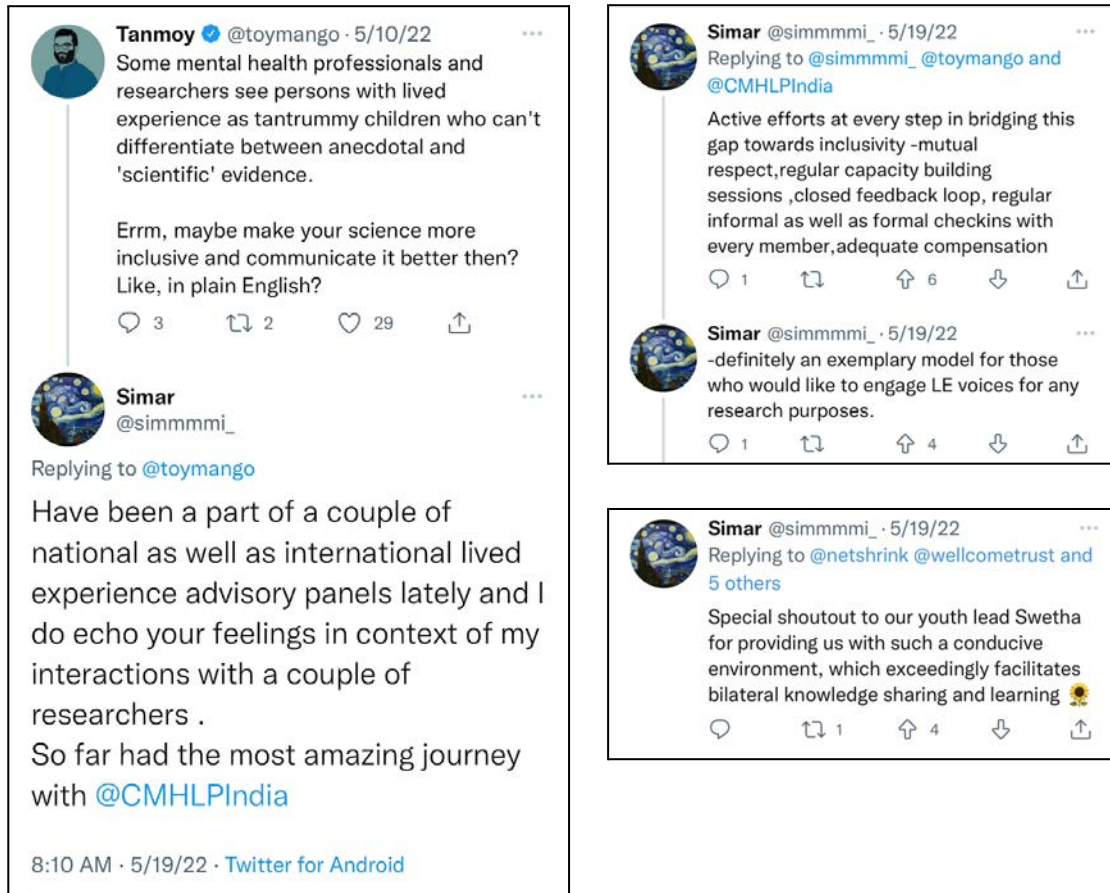
Figure 3.b.1: Indian YPAG member describing their engagement with the MindKind Study

As well as the climate of trust, YPAG engagement must be careful to develop a shared understanding across the group. To execute this, the facilitator(s) were considerate of youth's social and cultural context, how it might impact youth participation as well as their understanding, knowledge, and perspective of mental health. Connected to this, members of the MindKind research team were required to reflect upon their own use of jargon before engaging with youth. Topics like data usability and governance have a unique language which is not accessible to the majority of people. As such, any jargon or specialised language should either be omitted or carefully clarified by anyone working with YPAGs. Being proactive in confronting jargon improved youth confidence and therefore their involvement across MindKind.

Recommendations

YPAG Recruitment and Support

To enable effective YPAG recruitment and support, there should be key considerations around community engagement, accessible recruitment practices, and opportunities to

upskill. First and foremost, to challenge the notion that YPAGs only represent a small sub-section of a geographic site, teams should actively engage with community organisations to build strong relationships in the hopes of recruiting a broader spectrum of YPAG members. This would improve the extent to which YPAGs speak from multiple positions and experiences. Further to this, when undertaking recruitment for the YPAG, it is important to have accessible recruitment practices–such as the option to 'speak' or 'record' responses to questions. Written responses, which are largely in English, are sometimes contingent on previous educational experience. Ideally, YPAGs would also be delivered in local languages rather than only in English. Finally, once recruited, YPAG members should have access to training, support and upskilling opportunities dependent on their interests. Indeed, as recruiting youth from more diverse backgrounds may introduce power dynamics within the YPAG, reflexivity and positionality trainings could create an environment that is conducive to participation for all YPAG members. Sharing skills and resources is essential to forming an equitable and a less extractive relationship with YPAG members.

YPAG Transparency, Accountability and Feedback

Setting expectations for youth involvement is essential to creating a space of transparency, honesty, and accountability. These parameters should be set from the start and YPAGs should know what is possible and not possible to change on the project. Having made their contributions and sharing insight, there should be an insight tracking mechanism which understands the extent to which YPAG input is or is not shaping the project more broadly. Airtable was used as a mechanism to facilitate these insights but this was not a core component of the youth integration strategy. As such, despite its use, Airtable could potentially have been used more effectively, most notably through project leads providing prompt feedback about youth insights which can be regularly reported back to YPAG members by PYAs.

YPAG Engagement

Following recruitment and the setting of role boundaries, engagement is the key next step to working with YPAGs. PYAs should have had access to a YPAG engagement guide or trainings which could have supported youth involvement from the start. Tips such as using simple language, using pop-culture references, avoiding research jargon, and the importance of building trust and rapport were noted as especially important learnings which youth would have benefitted from had they considered them closely at the start. Positively, as this study is testing feasibility, there is a lot which could and should be learnt from youth involvement so an engagement guide could be developed for future use.

Finally, engaging with YPAGs presents different obstacles depending on the geographic context. With a number of challenges related to technology and internet access, it would be sensible to consider a digital equity fund within the project itself to be used specifically for these means. More broadly, this fund could be used to support engagement in a digital context for those YPAG members who may experience obstacles to being meaningfully involved.

c. Global Youth Advisory Panel

Approach

The Global Youth Advisory Panel comprised 3-5 representatives from each of the 3 country sites (the size of the panel ranged from 9-15 throughout the project). PYA were also invited to attend Global Youth Advisory Panel meetings along with their panel members. Each youth

panel underwent its own process of identifying and selecting youth to serve on the Global Youth Advisory Panel, and generally, interested YPAG members submitted statements of interest and/or were voted on by their in-country panel members. Youth were eligible to serve on the Global Youth Advisory Panel if they had access to WhatsApp or an equivalent technology platform. They received honorarium (in all three sites) and data (in South Africa) for their participation.

The Global Youth Advisory Panel met approximately monthly throughout the project period. MindKind team members from the University of Washington organised, scheduled, and facilitated meetings and recorded meeting notes in AirTable. Other project team members also attended Global Youth Advisory Panel meetings as appropriate to present on specific aspects of the project and solicit youth feedback. The Global Youth Advisory Panel members were seen as representing the voices and interests of their in-country youth panels and this group was a place to consolidate decisions made across the different in-country panels and decide on similar and different approaches based on the needs across the three settings. Global Youth Advisory Panel members were also asked to share back with their in-country panels key topics discussed at these meetings and summaries of these meetings were shared with the broader Steering Committee as needed by University of Washington team members.

Learnings

There were five key learnings arise from the Global Youth Advisory Panel meetings and operations:

The importance of thoughtful recruitment approaches

This group was recruited through the in-country youth panels, and the PYAs emphasised the importance of equitable and transparent approaches to appointing youth panel members into the Global Youth Advisory Panel. The in-country panels solicited nominations for the Global Youth Advisory Panel (either written applications or verbal statements of intention) and in-country youth panel members then voted on who they would like to represent them at the Global Youth Advisory Panel forum. In a project like this one with multi-tiered approaches to youth engagement, youth appreciated having democratic processes to membership in additional youth panel activities. This seemed to work well in ensuring that in-country youth panel members supported and felt supported by their Global Youth Advisory Panel representatives.

Challenges with conducting meetings across time zones

The Global Youth Advisory Panel included members across four different time zones which posed challenges with scheduling and data/internet access for all members. Inevitably, meeting times and the Zoom platform worked better for panel members from some geographic areas than others which created lopsided engagement. Inconsistent electricity and internet access meant that South African youth panel members were often not available on the calls. This created inequities in participation and meant that it was often difficult to hear the perspective of South African youth in this global youth forum.

Aligning meeting cadence with project decision making

The Global Youth Advisory Panel met monthly which, during the beginning of the project was too infrequent, and during the latter stages of the project was too often. In the early stages of MindKind, decisions often needed to be made quickly and it was difficult to meaningfully engage this panel due to scheduling difficulties and the need to build in time to develop group cohesion and capacity-building. While the youth panel members appreciated having a predictable monthly meeting cadence, which was not too overwhelming given their other in-country youth panel responsibilities, a more flexible meeting approach that aligns with key project decisions and capacity building needs may have been preferable.

Challenges creating group cohesion in a virtual setting

The Global Youth Advisory Panel consisted of youth across all three in-country panels, who have never had the opportunity to meet one another in person. It was challenging to create group cohesion in this group when panel members were only together virtually once a month for an hour-long meeting. This sometimes manifested in reluctance to speak up during meetings.

Enjoyment of "guest speakers"

We initially conceived of this group having monthly meetings with the same facilitator (from the University of Washington) who would present on key project findings and operations and engage the group in discussions. However, partway through the study we also included "guest speakers" from other parts of the project–researchers at Sage, the Wellcome Trust–and the youth panel members appreciated hearing from these different individuals about specific components of MindKind. While it was helpful to have consistency in knowing that the University of Washington team would be the touchpoint for this group, it was also important to vary the content and speakers throughout the project to keep youth panel members engaged.

Recommendations

Based on these learnings we have identified four key recommendations for future studies including a Global Youth Advisory Panel group:

Set clear expectations for recruitment, reimbursement, and engagement

It is critical to be clear at the outset about how youth will be recruited into a Global Youth Panel, particularly in instances where they are being recruited from an existing panel or other youth engagement activity. It is also important to be transparent, consistent, and timely in reimbursing youth for their participation and data usage and to think creatively about approaches to maintain engagement for youth across time zones (e.g., asynchronous meetings, varied meeting times, recorded sessions with paired activities outside of meetings). This will help improve equitable participation and ensure idea generation across youth from all country contexts.

Provide a clear description of the goal of a Global Youth Panel

This project had several youth panels and it was important to set clear expectations about the role of youth in the Global Youth Panel and how participation in this panel would differ from their in-country youth panels. The Global Youth Advisory Panel was initially conceived of as a space to consolidate ideas discussed across the three in-country panels. However,

those expectations were infrequently discussed or adhered to which sometimes created confusion about the purpose and structure of this panel.

Provide adequate time for team building activities

A multi-hour "retreat", in person workshop, or other forum would have been very helpful for building youth panel cohesion, allowing the group members to get to know one another, and encouraging participation during the Global Youth Advisory Group meetings. These team building activities could also include reflexivity, positionality, and cultural humility training at the outside to ensure that youth reflect on their own social and cultural identities and power dynamics in the group and to create a safe space for future dialogue.

Clear reporting structure

Although we intended for the Global Youth Advisory Panel members to be representatives of their in-country youth panels, panel members did not regularly have opportunities to share what was discussed during their in-country panels or to report back to their panels about the Global Panel activities. Clearer reporting structures and expectations would be helpful in empowering youth to be representatives of their in-country youth panels in the future.

4. External researchers: the Data Usability Advisors Group

Abstract

The MindKind Data Usability Advisors Group (DUAG) formed another element of the project governance structure. We recruited and selected members of the DUAG so that a relatively wide range of scientific disciplines and a variety of people involved in youth mental health research or services would be represented. Given the technical specificity of the project and associated deliverables, we found that people whose research interests and activities were most relevant to the study participated more frequently. Nevertheless, the majority of these external researchers provided meaningful perspectives on a broad range of use cases for the databank. Their input on preferred governance models, feedback and evaluation of databank accessibility and usability, resulted in specific design recommendations for the databank. The group consistently raised the importance of maximising the diversity of youth participants in the study (advisors and study participants), promoted youth-centred participatory research methods (including mentored citizen science approaches), and advocated for measures to ensure the equitable use of data generated by the current study and future uses of a databank.

a. Group construction and orientation

Approach

The MindKind Data Usability Advisors Group (DUAG) were recruited to advise on the design aspects that would make the GMHD useful for research inquiry. To ensure that the databank would meet the needs of its anticipated users, we selected a diverse group of researchers and clinicians from across the globe, including the three primary study countries. We specifically sought a disciplinarily diverse group of researchers, with the hope that a future databank would ideally offer opportunities for a broad range of science relevant to youth mental health. The group included members of the Wellcome Active Ingredients groups, and members represented psychiatric epidemiology, anthropology, neuroscience, big data science, adolescent mental health interventionists, clinically oriented practitioners, as well as experts in open science and data sharing. Our group included researchers across the career spectrum–from early stage investigators to senior research leaders. The team possessed expertise in the range of methods that the MindKind Study employed: qualitative, quantitative, and mixed methods.

Initial Meetings and Feedback

Within the first three months of the study, we met with DUAG members twice to orient them to the project and respond to questions. We elicited their initial feedback through group discussion and through a survey administered by the coordinating team. DUAG members shared their thoughts on these key areas: data collection, youth participation, country contexts, costs, frequency of data collection, and data usability. We wanted to assess whether members of the DUAG would use this databank, what would make them more likely to use it, and how would they use the databank.

Box. 4.a.1: Data Usability Advisory Group Members

- Prof. Ian Hickie | University of Sydney | Australia
  https://www.sydney.edu.au/medicine-health/about/our-people/academic-staff/ian-hickie.html
- Dr. Christian Kieling | Universidade Federal do Rio Grande do Sul | Brazil
  https://www.researchgate.net/profile/Christian_Kieling
- Dr. Jane Roskams | UBC | Canada
  https://www.zoology.ubc.ca/person/jane-roskams
- Prof. Shekhar Seshadri | National Institute of Mental Health and Neurosciences (NIMHANS) | India
  https://www.researchgate.net/scientific-contributions/40039421_Shekhar_Seshadri
- Dr. Rangaswamy Thara | SCARF | India
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  https://www.linkedin.com/in/chantal-goliath-12984479/?originalSubdomain=za
- Dr. Lindsay Dewa | Imperial College London | UK
  https://www.imperial.ac.uk/people/l.dewa
- Dr. Tatiana Salibury | Kings College London | UK
  https://www.kcl.ac.uk/people/tatiana-taylor-salisbury
- Prof. Ann John | Swansea University | UK
  https://www.swansea.ac.uk/staff/medicine/research/johna/
- Prof. Ed Watkins | University of Exeter | UK
  https://psychology.exeter.ac.uk/staff/profile/index.php?web_id=ed_watkins
- Dr. Vince Calhoun | Tri-institutional Centre for Translational Research in Neuroimaging and Data Science (TReNDS) | USA
  https://trendscenter.org/vince-calhoun/
- Dr. Mike Milham | Developing Brain, Child Mind Institute | USA
  https://childmind.org/bio/michael-p-milham-md-phd/
- Dr. Katherine Foster | University of Washington | USA
  https://psych.uw.edu/newsletter/winter-2020/faculty/faculty-spotlight-dr-katherine-foster

Survey

In October 2020, we conducted a survey to gain DUAG perspectives on how to ensure the usefulness and usability of the prototype databank for researchers. A total of 24 participants (15 DUAG advisors, 8 researchers, and 1 citizen scientist) responded. The respondents conducted or supported research in 25 countries, with the majority working in mental health services, behavioural/cognitive/developmental science, and mental health epidemiology. All respondents worked with the adolescent/child population, and more than half worked on depression and anxiety disorders. The remainder of the participants were evenly split between work with suicide and non-condition specific mental health services.

Respondents represented 5 countries: the US (9), South Africa (6), UK (5), India (3), and Brazil (1). Most participants (69.6%) had university/academic affiliations, while others worked with NGOs/Nonprofits (21.7%), health care (21.7%) and government (4.3%). Within these organisations, respondents worked as researchers, educators, clinicians, program implementers, and policy makers. The survey elicited feedback on 2 primary areas: the usability of the databank and the value of the databank.

Usability of the Databank

Respondents ranked seven attributes that would make a global mental health database most useful for them. Lower numbers represent greater importance.

1. Ability to prospectively deliver and test interventions with participants
2. Ability to propose new variables or new data streams
3. Ability to collect data from non-smartphone platforms (e.g., SMS, paper)
4. Ability to collect data on mental health outcomes other than depression and anxiety
5. Ability to collect data on exposures other than the active ingredients
6. Ability to enrol your own cohorts into the data collection
7. Ability to communicate directly with participants that contributed data and potentially enrol them in future studies

Value of the Databank

Respondents described the value of the databank for researchers and young people; they shared anticipated challenges each group might face when accessing and using the data.

Value identified for researchers:
- Active and passive and longitudinal and EMA formats
- Understanding [youth] developmental variation
- Formative data to support research applications
- Ability to study diverse populations with adequate power
- Valuable to those working with youth
- Intervention development
- Identifying potential moderators and mediators of vulnerability/resilience
- Continuous variable data collection

Value identified for young people:
- Youth participate actively in data collection process
- Youth can understand their mental health better
- Value for non-researchers in the results

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The DUAG members also believed the databank would provide valuable learning for clinicians working with young people.

Challenges identified:
- Lack of [diverse] socioeconomic representation [given need for cell phones and data]
- Collecting qualitative data
- Unclear how interventions would be developed
- Some researchers may need training in passive data collection and open databanks

Please see Appendix I.4.a.1 for a detailed set of use cases.

Importantly, the DUAG raised questions and commented on issues that would influence the quality of the data collected during the proposed study and a future databank (Table 4.a.1). If methods development were a future focus of the databank, exploring the best approaches to integrate "disparate" types of data would be an important effort. They warned of the risk of bias, cautioning the research team to be mindful of what biases might be present through sample selection and recruitment. Equally important, bias (real or perceived) carried the risk of discrediting the work of the databank.

Table 4.a.1: Considerations for data collection
Data collection - Consider measures that assess strengths and weaknesses - Consider who the population is: at risk, symptomatic, or healthy - Generally, people won't volunteer or contribute [data] over longer periods unless it is clearly useful at both a higher level and the individual level.
- Need collection of circadian rhythm and sleep patterns across seasons. Optimally, collection is possible over years. Typical periods [of observation] are not long enough to measure changes and trajectories; yet there are large variations within periods (e.g. sex differences, brain development)
I think there is a richness that comes from both granular data and sort of situating that in a broader context of development is so critical. We could think of a longitudinal burst design, where we're having a hybrid approach, **collecting rich granular data intermittently on top of more extensive batteries of data collected over longitudinal periods across local developmental times**
The more often people put their data in, the more you can see the associations that really matter to that individual. **Feeding that data back to people, in ways that are really useful, encourages them to stick at it** and basically work out for them, what is the relationship between their sleep, their activity, etc. Unless there is a feedback system, to those who provided data, the likelihood to continue that would be very low.

DUAG members raised questions about diversity and inclusion in the study sample and among other youth participants. They discussed the limitations of recruiting a truly economically diverse study sample, recognizing that the most vulnerable youth in some settings would be excluded by virtue of not having cell phone or data access. Concerns about diversity extended to the youth advisory roles; DUAG members advocated for inclusion of youth who were not solely "from middle and upper class backgrounds."

Learnings

We recruited and selected members of the DUAG so that a relatively wide range of scientific disciplines and a variety of people involved in youth mental health research or services would be represented. Given the technical specificity of the project and associated deliverables, we found that people whose research interests and activities were most relevant to the study participated more frequently. In hindsight, we were not able to successfully solicit insight from a broader group of researchers and clinicians whose work was not as clearly aligned with the study goals. Nevertheless, many of the themes raised by the DUAG in the first quarter of the study activities (when participation was most robust) echoed discussions among the Steering Committee members.

DUAG members valued the potential to collect active and passive data longitudinally from young people using the tools of the databank. The prospect of a databank as a platform for developing and testing interventions as well as the ability to introduce new variables and datastreams ranked among the top priorities for the group. At the same time, group members valued the possibility of a platform that could connect a broad variety of stakeholders committed to improving youth mental health.

Particular points of engagement

We interacted with the DUAG when study deliverables required their input and on a quarterly basis through email updates or informational sessions. Research team members often participated in DUAG meetings, contributing details about site-specific activities. The approach to working with the DUAG was distinct from the approach to working with the youth advisors–there were significantly fewer touchpoints. Early in the study the decision was made at Sage that given the frequency of interaction with the research team members and the breadth of expertise on the team, the research team provided ample guidance and feedback on most study design and protocol questions. We engaged the DUAG members for the following tasks, specifically, that aligned with key decisions or deliverables.

- Initial use case brainstorming (Section 4.a)
- Preferred data governance models to compare with YPAG preferences (Section 8.b)
- Beta-testing of data access and usability (Section 9)
- Evaluation of access and usability by the DUAG and members of the wider research community (Section 9)
- Evaluation of a draft protocol for data access by members of the wider community (Section 9)

Recommendations

To optimise DUAG participation for each phase of the study, consider engaging a broad DUAG for an initial phase (e.g., first 6 months of the study). This permits a broad set of input at the start of the study. For later stages of the study, when greater familiarity with the technology being developed is valuable, consider retaining a smaller DUAG with the requisite experience. See Section 9 for recommendations related to use cases, access, and usability evaluation.

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b. DUAG project perspectives

Approach and Learnings

Two issues stimulated considerable discussion among the DUAG and researchers: inclusive participation in the research and equitable access to the data.

Inclusive Research Participation and Citizen Science

We invited the DUAG to reflect on opportunities for citizen science through the databank. In response, DUAG members promoted approaches to research that centred research participants and facilitated their feedback—from co-production of research questions with youth to data collection methods that allowed participants to view their own data in the context of larger study data.

They were enthusiastic about the prospects of the databank as a platform for citizen science. Citizen science projects could have educational and outreach components, which guided citizen scientists in decision making. People who participate can learn the fundamental components about what they are doing through the research and what its significance may be. Through engaging citizen scientists in the research, research teams are educating people about things they care about. In the MindKind context, the databank is creating a space where people can safely ask the questions they want to know about mental health.

One member cautioned that there is a mentorship component to citizen science with young people. Important to consider whether someone is helping the youth design projects because mentorship is necessary to help young citizen scientists get what they want out of the experience. This member noted, "Citizen science is different from just 'crowdsourcing' research questions; youth don't really get anything out of 'crowdsourcing' model."

These exemplars of citizen science were described:
- Neuro Stars: A question and answer forum for neuroscience researchers, infrastructure providers and software developers. Young people in research training (graduate or post-doctoral) pose questions and other researchers can answer those questions for them. This platform provides a way to get answers from an informed group
- Health Data Research (HDR) UK COVID youth survey: This initiative organised internships (100 Black Interns) with researchers. They create videos or infographics for research projects. "These internships are quite powerful for youth to have."

Access and Equity

As the team neared the launch date for the MindKind website and app, the DUAG reflected on the implications of open access data. Could commercial entities be eligible, as researchers, to receive data? The group debated the consequences of permitting commercial use of the data. On the one hand, if commercial entities conducted research with the databank's data, could tracking their utilisation confer protection against misuse? On the other hand, could for-profit companies be trusted to use the data ethically? Members agreed that although youth give their data to social media companies already (e.g., Instagram, TikTok), research use needed to be held to a higher standard.

Should the data be available for powerful organisations to create IP and profit from its use (monetarily or otherwise)? Ideally, companies would share the IP with the communities they studied. A problematic outcome would be if companies enforced intellectual property over the study results. A concern was that a private company could develop some IP from the data and the communities who contributed their health and data would not be able to access it.

Similar concerns extended to powerful academic groups. Members agreed that academic groups can create IP and profit from the data (scientifically and/or financially), and highly-resourced academic institutions can produce products from the data faster and with higher "impact" (i.e., publications). ("*Big institutions often swoop up and publish everything.*") Members posed this question: "How do we avoid colonial policies of data ownership by those in power?"

Recommendations

- Build safeguards for IP in an Open Database to ensure equity.
- With respect to equitable access one could place an 'embargo' on data; however, this would restrict local researchers to their own in-country data, not cross-country.
- Place restrictions on authorship or support efforts to increase capacity at the local level to "even the playing field."
- A more positive approach to "embargos" would be preferred. Instead of limiting authorship, stimulate researchers from LMICs through specific grants, etc., to use the data, rather than limiting use of the data to a specific group of researchers.

5. Ethical and Regulatory Processes

Abstract

Addressing the ethical and regulatory requirements for even a feasibility study for a global repository banking data on mental health from youth across multiple jurisdictions is complex and time consuming. While the overall ethical principles may be aligned across jurisdictions, the processes for reviewing the research and obtaining all necessary approvals differ. Consultation with local experts was critical to pre-emptively addressing potential concerns about the project governance, cultural competency, and/or international data sharing, and obtaining the necessary approvals. However, the limited capacity of ethics boards during the COVID-19 pandemic caused significant delays both as ethics boards prioritised projects on COVID-19 and as reviewers themselves fell ill and could not attend meetings.

a. Across Countries

MindKind is a complex multi-national research project with unique ethical and regulatory challenges. First, MindKind includes both quantitative and qualitative study arms. The quantitative arm of the study collects data remotely through a dedicated smartphone app while the qualitative arm includes direct contact with research participants. Second, the focus of the research on mental health and well-being, and the age of the research participants (16-24 years) justifies added caution and oversight scrutiny. Third, the main study Principal Investigator and the funder were from the Global North (US and UK respectively), with research participants from high-income (UK) and low- and middle-income countries[4] (South Africa and India). Fourth, privacy laws and regulations evolved throughout the project. For example, Brexit (the UK's departure from the EU) became effective after the start of the project. This state of regulatory flux complicated the process of ensuring that the MindKind Privacy Policy reflected the diverse privacy laws applicable in the project. Fifth, designing a valid in-App informed consent to be released in multiple countries and obtaining a valid informed consent required cultural awareness and sensitivity to local context upfront. Sixth, the study information websites, leaflets and informed consent needed to be translated in languages that the majority of in-country participants understand.

Approach

In addition to local PIs and site leads, in-country ethical and legal experts were consulted who could advise on the intricacies and nuances per country and region. We also consulted the US Department of Health and Human Services' International Compilation of Human Research Standards[5] to identify the applicable laws, regulations, and guidelines. In each jurisdiction, ethics boards and research oversight authorities needed to review and approve the research prior to its implementation and any protocol modifications thereafter.

We reasoned that combining the two study arms into a single protocol submission would facilitate the reviewer's understanding and ultimately accelerate approval. We also addressed, both in the protocol and in informed consent, questions about the processing and international transfer of data.

We collaboratively developed the protocol and study materials. After extensive iterations with the PIs, technical team, design team, PYAs, and YPAG DUAG members, we submitted protocol amendments to the ethics boards and relevant oversight authorities in each country:

> (1) to clarify study details and provide additional explanation,
>
> (2) to incorporate suggestions from YPAGs to improve user experience,
>
> (3) to reduce participant burden during the electronic consent process.
>
> (4) to address reviewers' comments.

Learnings

Expertise from site leads and PIs enabled the ethical and regulatory processes to proceed relatively smoothly despite site- and country-specific differences in ethical oversight and data handling requirements. The collaborative approach enabled teams to learn from each other and better address questions from oversight authorities.

During the review process, similar questions and themes emerged across all jurisdictions, including:

- *Is the MindKind app a medical device?*
  Medical devices are regulated under distinct authorities than research devices. The MindKind app is not a medical device. It is not intended as a medical care or diagnosis medical device.

- *What roles are each party responsible for?*
  Local site PIs are considered data controllers responsible for the design and implementation of the qualitative arm of the study. They were involved in storing and processing data locally.

- *What and how much data does the MindKind app collect?*
  The app collects active and passive data streams with participant's consent, but does not access other apps on the participant's phone, nor does it access emails, text, photos, etc.

- *What support is given to those in distress?*
  Curated third-party, online mental-health resources and emergency services are listed on the mental health resources page of the MindKind website. These contacts are also highlighted in the study app. A study contact in each country is designated to triage questions from participants.

- *How will data be processed and accessed by international teams?*
  The App data, without the participant's name, are transferred electronically and combined. The qualitative data transcripts are de-identified prior to being shared with international teams. Participant identity is not shared.

- *Are the data collected necessary to fulfil the aims of the study?*
  The collection of personal data must be justified and proportionate to the aim of the study.

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Some questions were more localised. For example, the challenge of high costs for data and the need to refund participants seemed to be largely confined to South Africa and to India to a lesser extent. Similarly, what information and research documents required translation from English was a local decision.

The ethics boards in each jurisdiction reviewed all materials that a potential participant would see. This included the advertisements, the study information leaflet, the content of the study website, all support and resources available, the study privacy policy, informed consent, and the surveys. The ethics boards also reviewed the technical security measures and data handling methods.

Some regulatory processes were faster than others but in the end, all sites obtained the necessary approvals to start the data collection, showing that such international efforts are feasible, even under complex ethical, legal, and regulatory regimes.

Recommendations

The preparation of materials to be submitted for ethical and regulatory approval is complex and time consuming. Designers of a future GMHD should anticipate needing to notify ethics boards of protocol revisions and to submit amendments. This was particularly the case in this project where the app development and ethics board submissions occurred in parallel, due to the tight timeline for the feasibility study.

Ethical considerations and concerns about data sharing and data storage were similar across ethics review committees. This highlights the importance of tackling these concerns upfront when writing the research protocol with very clear and detailed descriptions of these processes provided in simple language that avoids too much jargon. This applies to communication with both the ethics committees and participants. That means the participant information leaflets and consent documents should also take the same approach so that they are easily understood by most participants, the standard for which in the US is targeting the reading ability of the average 12-14 year old.

b. By Country

India

Approach

To ensure compliance with ethical and regulatory bodies in India, the site team in collaboration with Sage applied for (i) institutional ethics approval at the Indian Law Society, (ii) registered with the Clinical Trials Registry, and (iii) Health Ministry Screening Committee (refer to Fig.5.b.1 for details). The applications were developed based on the core protocol and in compliance with national guidelines such as the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (ICMR, 2017), and the relevant data laws of India (e.g., IT Act Rules, 2011; Personal Data Protection Bill, 2019).

The team applied for ethics approval to the Indian Law Society Ethics Committee (ILS EC) on 3 March 2021, followed by an online meeting of site lead with the Ethics Committee on 27 March 2021. The EC proposed changing the status of risk to study participants from 'mild' to 'moderate' given the nature of data collected, age group, and inclusion of people with lived

experience. The site lead clarified that the study app was not going to provide any direct or indirect mental health care support. Ethical approval was received on 6 April 2021. The team submitted the amended proposal, translated recruitment material and qualitative educational materials on 14 September 2021.

Subsequently, the study was registered with the Clinical Trials Registry India (CTRI). CTRI is a free online public record system for registering clinical and non-clinical studies to uphold data transparency, accountability, and ethical practices in research. The CTRI registration number was assigned on 16 April 2021 (CTRI/2021/04/032873).

This was followed by submission to the Health Ministry Screening Committee (HMSC) constituted by the Department of Health, Ministry of Health and Family Welfare, Government of India. HMSC is a government screening committee that 'reviews Indo-foreign collaborative proposals in the field of biomedical health research'. The HMSC meets once every 2 months to review submissions submitted prior to the meeting deadline. The proposal was submitted to the HMSC on 30 April 2021 for it to be reviewed in the June 2021 meeting. However, due to the COVID-19 pandemic, the timelines for review were delayed. The site lead was in touch with the HMSC to request for updates on the review process since submission of the proposal, to avoid delays in the study timelines.

The team received queries from the HMSC regarding the methodology and asked for clarifications on institute specific regulatory documents such as Foreign Contribution Regulation Act permission in July and August 2021 (refer to Appendix I.5.b.1, pages 2-10). The team responded to these queries however, on 22 September 2021, the HMSC rejected the study proposal (reasons mentioned in the Appendix I.5.b.1 on page 11), the primary concern being that personally identifiable data from Indian participants would be stored on the US server managed by Sage.

The site lead appealed against the decision on 29 September 2021 and requested a fast-track of the appeal considering the project timelines. The Chairman, HMSC, granted a provisional approval on 1 November 2021 (refer to Appendix I.5.b.1, page 11) on the condition that all personal identifiable information of the participants will be retained within the country and only de-identified data will be shared with foreign collaborators. The site team and Sage worked on a solution where all the consent forms of Indian participants were emailed to the site team, ensuring all personal identifying information of Indian participants would be retained within the country. The site team then printed and physically stored the consent forms in a secure location as per the ICMR guidelines (2017). The team submitted the amended protocol on 15 November 2021, following which the formal approval was issued on 1 December 2021 (refer to Appendix I.5.b.1, page 13).
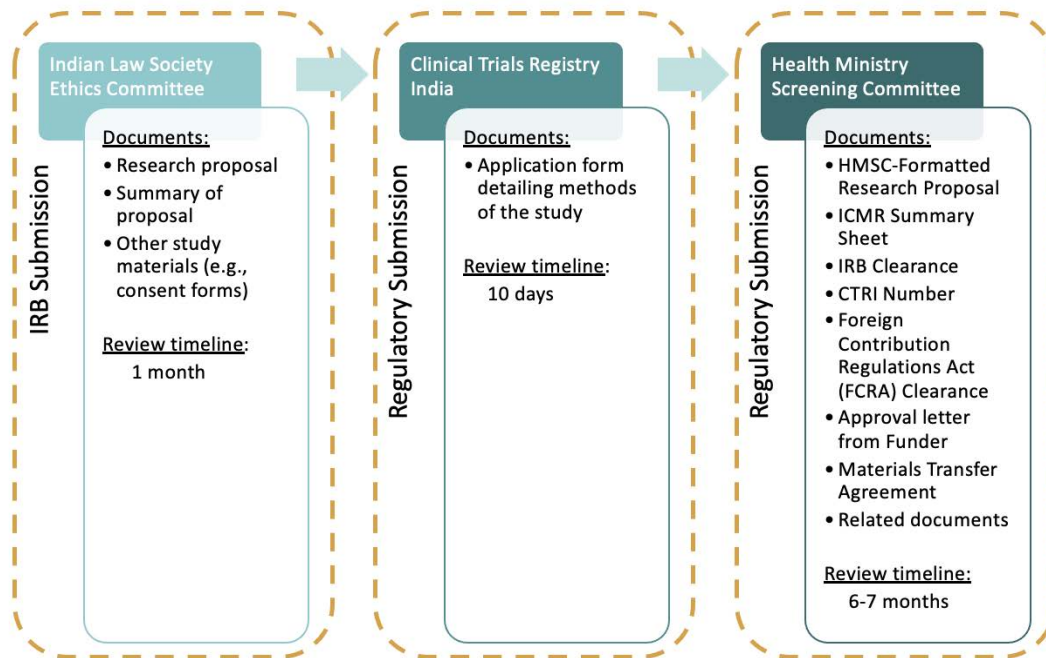
Figure 5.b.1: Ethical and Regulatory Approval requirements at the India site

Learnings

Scoping of regulatory and ethical requirements for a digital intervention, expertise of the site lead, and support from the Sage team enabled the proposal to meet the required standards. While the final regulatory approval was delayed in comparison to other sites due to unforeseen circumstances; transparency and willingness to adapt the protocols proved helpful. Sage and site teams were able to have open conversations and brainstorm solutions to resolve the concerns raised.

Both CTRI and HMSC sought clarifications and details about the research methodology (e.g., sample size calculation), the statistical analyses to be conducted (e.g., potential confounders) which were not necessarily designed for a feasibility study. It helped to have the entire team of experts respond to the queries in a timely manner.

Bureaucratic delays, added with the challenges of the pandemic delayed the ethical approvals for the India site. In addition, the nature of the proposal, funding source, subject matter, and the approaches to data handling needed to address reviewers' concerns and adopt practices that adhered to regulatory compliance.

Recommendations

Distributed leadership on different tasks amongst teams is a helpful way to receive responses in a timely manner.

Giving adequate space and time to account for unanticipated delays across sites was helpful to achieve the overall aims of the study.

<u>**South Africa**</u>

Approach

There were two sites where the research was to be undertaken, in two different provinces, (Gauteng and the Eastern Cape). The team chose Walter Sisulu University as the primary submission site for seeking ethical approval as one of the two principal investigators had had prior experience of working with the committee. The idea was that once Research Ethics Committee (REC) approval had been granted, it would apply to both sites included in the proposal. This is allowed in the South African research regulatory context due to the common overseeing body that resides at national level, with which all research and ethics committees are registered. This allows for ethical approval received in one province for a multisite research project to be valid across provincial boundaries.

There were a few specific ethical requirements for implementation of the protocol in South Africa. For example, the consent forms and participant information leaflets are required to be translated into local languages. This is to ensure that people who are interested in joining the study can be informed in the language with which they are most comfortable. However, this requirement did not extend to the MindKind Study app content (e.g., surveys and responses) as participants were recruited from mainly a tertiary education centre where the language of instruction was English. Another specific requirement was to reimburse the reasonable cost of connectivity and smartphone data usage without unduly influencing potential participants to join the study. The research team evaluated these costs and designed a process to administer the requests for reimbursement.

The protocol was submitted for review to the Walter Sisulu University Human Research Ethics Committee (WSU REC) on 16 March 2021. We expected that the review would take at least one month, especially during the COVID-19 pandemic when many meetings were cancelled. In fact, the process took longer due to REC member illness and review reassignment.

On 24 May 2021, the WSU REC coordinator asked to verify approvals from the other MindKind sites. This is not unusual in cases where the reviewer is new to the research topic. The study team was able to share approvals from India (ILS Ethics Committee) and the US (WIRB IRB). On 2 June 2021 the WSU REC approved the MindKind Study and the study team received the WSU REC Clearance Certificate.

The study was submitted for renewal to the WSU REC on 9 May 2022. This submission to the WSU REC included a study progress report, a protocol deviation report, copies of the consent forms for both the quantitative and qualitative study arms, and a link to the drafted protocol report. The

Figure 5.b.2: Journey of Ethical and Regulatory Approval at the South Africa site

study team received renewal approval Clearance Certificate from the WSU REC on 13 May 2022.

Unlike in India and the UK, in South Africa there was only one body that was required to give ethical approval. Although there was an initial plan to recruit from public health institutions which would have required submission of the proposal for ethical approval with the Department of Health Research and Ethics Committee, in the end, recruitment took place at institutions of higher learning which cancelled out the need to seek approval from the Department of Health in South Africa (Figure 5.b.2).

Learnings

- The major challenge was translation of consent documents and participants' information leaflets. This is because words and concepts that sound straightforward and uncomplicated in English do not always have equivalent terms in indigenous languages. This is especially so when it comes to technical medical terminologies or technical IT language. This therefore necessitated the hiring of professional translators to overcome this challenge.
- Another challenge which touched on the ethical aspects of the study was the cost of connectivity and data which is very expensive in South Africa. As much as the research team could not sanction a research process which entailed paying the participants for taking part in the study, the unaffordability of data and the fact that the research process relied heavily on internet connectivity meant that the team had to find a way to compensate the participants for all data costs incurred. Payment of data for participants was sanctioned by the ethics committee.

Recommendations

- It is possible to conduct multi-site research projects in South Africa, but they require proper coordination between sites and teams.
- Effective grant management systems have to be fully functional to enable a project of this size to run smoothly.
- In research that uses technical or medical terms, translation of research documents may pose a challenge. In such instances it may be appropriate to submit a motivation to the ethics committee that indicates why such documents would still be understandable to participants even if they are not translated.
- Any research that involves use of mobile data or internet as part of the data collection process has to factor in costs of data to participants and research team members.
- A quality assurance process is advisable with research team members taking turns to check each other's entries where and when appropriate should there be any intricate work required as part of the data collection or collation process. It is advisable to have a senior on site supervisor who is able to support the research team to address any immediate challenges that may occur on site while busy with research activities.

United Kingdom

Approach

The Cambridge Psychology Research Ethics Committee is responsible for considering applications for ethical approval for research ethics in human psychology based at Cambridge University. Since the MindKind Study did not involve work with patients attending UK National Health Services, review by this committee was sufficient and we did not require additional review by the Health Research Authority. We were also required to obtain insurance, because the study involved human participants.

Members of the UK research team completed the standard application forms for ethical approval by the Cambridge Psychology Research ethics committee, using information from the Core Study Protocol. We also completed the standard application forms to obtain insurance for the study. The MindKind study was granted ethical approval on 21 June 2021, with reference PRE.2021.031. Insurance was obtained on 15 April 2021, with reference HVS/2020/3241.

Oxford University's Research Ethics committee was consulted on 24 June 2021 and confirmed that approval by the Cambridge Psychology Research ethics committee was sufficient because members of the research team from Oxford University were named as co-researchers on the approved Cambridge application and because staff/students from Oxford University were not directly recruited. The MindKind Study was logged in their database as external research, with reference number R73366/RE001.
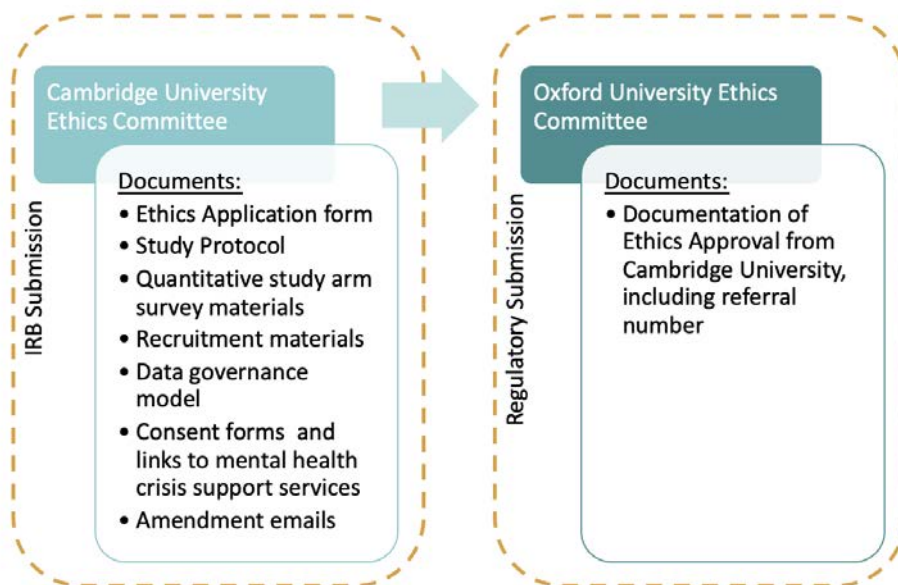
Figure 5.b.3: Journey of Ethical and Regulatory Approval at the UK site

Several amendments were submitted to Cambridge and approved, including:

- Extension of study period by 2 months.
- Approval of several additional recruitment strategies (creating a video for schools, asking to talk about the study for a few minutes at the beginning of lectures, and social media advertisements targeting parents of young people).
- Combining the originally planned 2x 1-hour qualitative sessions into 1x 2-hour sessions.
- Providing educational materials prior to sessions rather than watching them within sessions.

Learnings

Ethics committees had the following concerns which we needed to address, including:

- *Is the MindKind App a medical device?*
  Medical devices are required to be approved by National Health Service ethics and the Medicines and Healthcare Regulatory Agency. The MindKind App is not a medical device, and this was not required.

- *Are video recordings necessary?*
  Audio recordings would have been preferable to video as video recordings could constitute excessive/unnecessary collection of personal data. However, limitations of the Zoom platform meant that collecting video recordings was necessary.

- *Both Oxford and Cambridge are data controllers.*
  Whilst ethical approval was obtained at Cambridge, both sites were involved in storing and processing data so needed to be named as data controllers on information sheets.

- *Clarification regarding General Data Protection Regulation (GDPR).*
  It was required that we reference UK GDPR law on our Participant Information Sheet, rather than EEA-GDPR, since the UK is no longer in the EU.

- *Noting ethical approval.*
  All documents should reference the ethical approval.

- *Does the MindKind app collect data on use of other apps?*
  The ethics committee were concerned about passive data streams, and we clarified that these did not include collecting data from other apps.

- *Screening out children under 16.*
  The ethics committee asked us to direct under 16-year-olds who were screened out of the study to a page of mental health resources. This was created and added to the consent flow.

- *Clarity on transcription services.*
  Comments from the research ethics committee led us to change the plans to use CabbageTree Solutions for UK transcription. Instead, we used in-country transcription services that we had used for other projects.

- *Concerns about GDPR and international team's access to identifying data.*
  We clarified that UK transcripts would be de-identified prior to being shared with international teams. Cambridge University data compliance officers clarified that since Sage Bionetwork initiated the multinational research and collected identifiable data, this does not engage EU or UK data protection laws, as long as participants were aware of this.

- *Provision of support to those in distress.*
  We collated a list of third-sector and online resources, including information about emergency services in case they were needed. This sheet was linked from the mental health resources page of the website, and also linked if a participant does not meet study participation criteria.

Recommendations

Addressing the concerns raised by ethics committees within the first application would have speeded the process of gaining approval. In particular, clarity surrounding whether this is a clinical study of a medical device or an observational research study was important. In addition, the multinational nature of the study meant that questions around data protection law were to be expected and consulting compliance officers in advance (and making this clear in the application) would have avoided some delay. Finally, ensuring that adequate support signposting exists within the study is important, especially because the study team were not able to identify or meet clinical needs from the young people involved.

6. Quantitative study

Abstract

The quantitative study recruited young people from India, South Africa and the UK to participate in a 12-week smartphone-based study of mental health. The study protocol consisted of three 4-week rotations of "active ingredient" (AI) topics (body movement, positive activities, sleep and social activities). The study was designed as a randomised trial to test (1) the preference and acceptability of data governance models for the sharing of participants' data and (2) the effect of choice of AI in participant engagement. The consent rate was 42.3%, 56.8% and 60.6% for India, South Africa and UK, respectively with 1034 (475), 932 (387) and 1609 (1184) consenting (participating), respectively. While participants did show a preference for certain governance models, consent rate was similar regardless of consent model presented. Median engagement was 2 days (5 surveys), 6 days (6 surveys) and 11 days (8 surveys) for India, South Africa, and the UK, respectively. Participants given a choice of AI showed lower overall engagement than those presented with a fixed protocol.

a. Study design

The quantitative substudy was designed to assess the preference and acceptability of different data governance models and their effect on engagement patterns over time. Secondarily, it was designed to test whether choice of study topic affects study engagement.

Inclusion criteria

To be eligible for the study, potential participants must live in one of the participating countries (India, South Africa, UK), have access to an Android phone and be able to legally consent to their participation at each site (aged 18-24 in India and South Africa or 16-24 in the UK).

Basic demographic data

At the time of eligibility check, we also collect information about gender (multiselect)
- Man,
- Woman,
- Third gender/Non-binary,
- Transgender

    and/or

- Other

and history of lived experience with mental health challenges (multiselect)
- 'My mental health has interfered with my daily life'
- 'I have received support (outside my friends and family) for my mental health'
- 'I could have benefited from support for my mental health'
- 'I have not experienced any significant mental health challenges'.

For the purposes of analysis, selection of any of the first 3 options were categorised as 'reported history of lived experience of mental health challenges', and selection of the last option was categorised as 'no lived experience'.

Study design: governance models

Following eligibility checking and registration, participants were randomised to one of four different governance models designed to understand whether prospective participants of a future global mental health databank have a preference for data governance models which give participants more control over who can access the data and for what purpose, as well as to understand whether these preferences impact enrollment. In order to assess these questions, youth participants were randomised, in equal proportions, to one of four different governance experiences (Figure 6.a.1), the first of which (Group A) assessed preference, with the remaining three (Groups B, C, D) addressed acceptability of various data governance models.

In order to assess the preference of young people with regards to data governance, participants randomised to Group A were then prompted to select how researchers are allowed to access their data, and who controls access to the data. The selection of these options was informed by the disparate preferences expressed by youth co-researchers versus the DUAG.
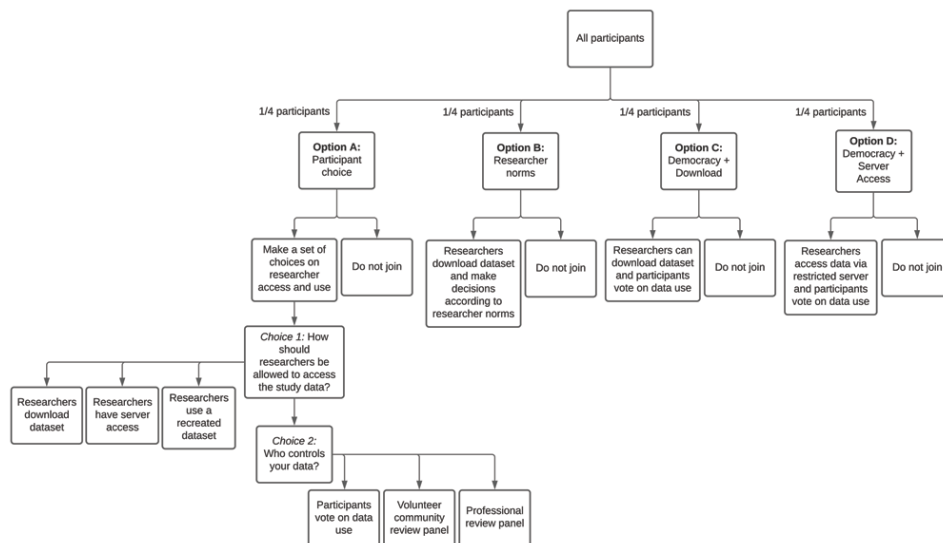
Figure 6.a.1: Governance study design.

Choice 1: How should researchers be allowed to access the study data?

1. Researchers should be allowed to download a copy.
2. Researchers should only be allowed to access the data in a secure server.
3. Researchers should only be allowed to see a recreated data set, not the real data. If researchers want to study the real data set, they have to ask the data steward to run their analysis for them. The steward only gives the researcher back the result, not the data.

Choice 2: Who controls the data?

1. Democracy: study participants who select this option get to vote on how the data is used, and the most popular terms are applied to all data regardless of how an individual votes. The results of the vote are shared with participants before data are shared. Any participant who disagrees with the vote may withdraw from the study.
2. Volunteer community review panel: participants selecting this option may choose to volunteer to serve as a data use request reviewer, taking one-week turns in this role on a rotating basis. Researchers will submit a statement telling the reviewers why they want to use the data. The reviewers will apply a set of criteria to decide yes or no. These criteria will be determined in advance by the whole group of volunteer reviewers.
3. Professional review panel: a paid panel will review data requests. This panel is a group of participants paid by the funder of the databank and may include research professionals (e.g., research ethics professionals). As above, researchers will have to submit a statement telling the reviewers why they want to use the data. The reviewers would decide yes or no, based on a set of criteria to which will be developed in advance by the group.

Participants randomised to Group A were asked to select their data governance choices prior to consenting. Additionally, participants who selected 'Democracy' for choice two were asked to provide their preference on four questions about data terms of use (see *Democratic Choice Voting* below) which constitutes their democratic vote (Figure 6.a.1).

In order to assess the acceptability of current governance standards relative to those that give participants a greater voice regarding how data are accessed and used, participants randomised to Groups B, C, or D were presented with a pre-specified governance model. These three 'acceptability' experiences were selected by the research team to test (1) whether democratic determination of data terms improves enrolment over current researcher-driven norms, and (2) whether limiting data access to a restricted server further improves enrolment. Specifically, the three models are:

- Research norm (Group B): This option presents current researcher community norms for data use, whereby researchers will be able to download a copy of the data from the databank following strict data security rules. Data may be used, unrestricted, by both commercial and non-commercial researchers.

- Youth informed democracy with download (Group C): Study participants vote as described in the Democracy Choice above. Under this model, researchers are allowed to download a copy of the data.

- Youth informed democracy without download (Group D): Study participants vote as described in the Democracy Choice above. Under this data governance model, data may only be accessed via a restricted server.

In order to mirror the experience in a typical study, participants were exposed to an informed consent specific to their data governance model and could choose to either join or not. They had no exposure to other potential governance models. In quantifying the difference in enrolment rates between participants in each group, we assess whether democratic

determination of access terms improves enrolment (Group C vs Group B), and whether restricting data download additionally improves enrolment (Group D vs Group C). We can also assess the effect of governance models on study engagement and retention.

Democratic choice voting

- Can my data be used by researchers to make a profit?
  - Yes, my data can be used by researchers to make a profit.
  - No, my data can NOT be used by researchers to make a profit.
  - I don't care if my data is used by researchers to make a profit.
- Do people have to pay to use my data?
  - Only commercial companies should have to pay to use my data.
  - Nobody should have to pay to use my data.
  - I don't care if people have to pay to use my data.
- How can my data be used?
  - My data should only be available for mental health research.
  - My data should be available for all types of health research.
  - My data should be available for broad research purposes.
  - I don't care how my data is used.
- How can results be shared with participants?
  - Results should be shared for free with the world.
  - Results should be shared in an easy to understand way with participants.
  - Both are important to me.
  - I don't care how results are shared with participants.

Study design: engagement

Following enrollment in the study, participants used the study app to complete daily activities (surveys) for the course of the 12-week study (Figure 6.a.2). The study posed questions about four active ingredients (AIs) which have been shown to influence mental health: sleep, body movement/exercise, social connections, and positive activities[2]. Participants focus on one of these domains in four-week rotations. For example, a participant may receive questions about body movement for weeks one to
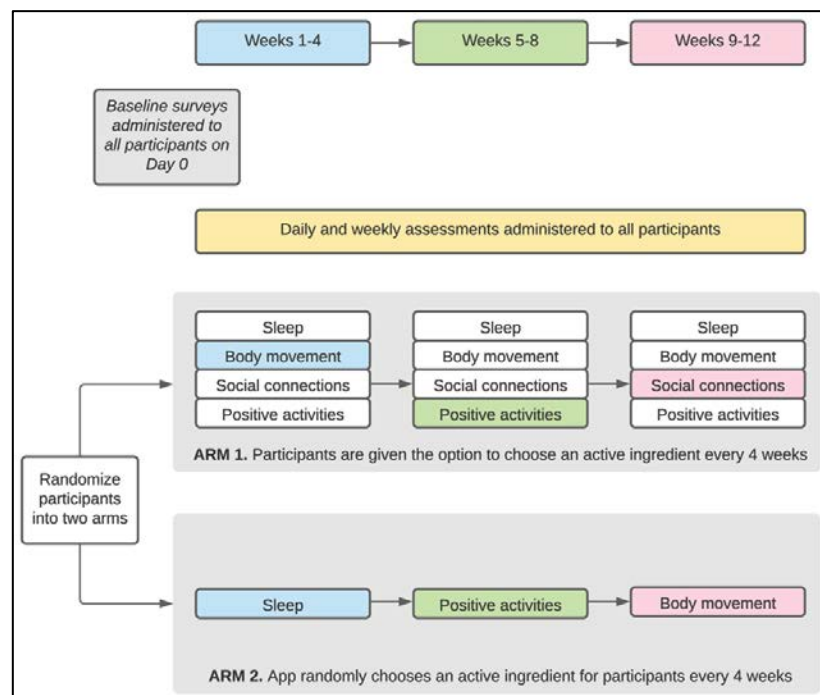

Figure 6.a.2: Engagement Study Design

four, positive activities for weeks five to eight, and social connections for weeks nine to 12. See the "*Data Selection*" section for more details on the content of these domain surveys.

In order to understand whether the choice of survey domain impacts a participant's short- or long-term engagement in the study, we independently randomised participants into two different arms (in equal proportion). Participants in the first arm selected their AI topic at the beginning of weeks one, five, and nine. Participants in the second arm were randomly assigned to their AIs for each of the three, four-week rotations (Figure 6.a.2).

b. Data selection

Approach

On enrollment, a baseline survey was administered to catalogue the participant's background and experiences with mental health. For ease of administration, these were divided into four sections. (1) 'About you' includes the topics demographics and socio-economic status (http://www.doi.org/10.7303/syn26067679.1). (2) 'Your environment' includes food security (USDA Food insecurity survey (six-item)[6]), neighborhood safety and cohesion questions (PhenX Neighborhood Safety, and PhenX Collective Efficacy)[7] and questions related to history of exposure to violence (http://www.doi.org/10.7303/syn26067679.1). (3) 'Your habits' includes questions pertaining to hobbies, physical activity and phone use habits (http://www.doi.org/10.7303/syn26067679.1). (4) 'Your health' includes questions pertaining to physical ability (WHODAS 2.0 (12-item)[8]), depression (PHQ-9[9]), anxiety (GAD-7[10]), and history and management of mental health (http://www.doi.org/10.7303/syn26067679.1). These baseline questionnaires were administered on study day zero (Figure 6.b.1), but only the "About you" survey was required in order to progress to the rest of the study. On the following completion of the "About you" survey, participants began their first AI-rotation for weeks one to four. The second and third rotations occur weeks five to eight and nine to 12, respectively (Figure 6.a.2).

As a safeguarding mechanism, we included warnings and/or prompts to mental health resources at key places in the surveys. For example, we included a warning about potentially triggering materials before the exposure to violence questions, with directions on how to find mental health resources. We also included these directions during the mood instruments (e.g. after the self-harm questions in PHQ-9).

Surveys and active data collection

The questions posed to participants throughout the study focus on the interplay between mood and four different AIs (sleep, social connections, body movement or physical activity, and positive activities) (Figures 6.a.2 and 6.b.1). Study participants were presented one AI at a time, in four-week rotations. On days one to six of the week, participants were asked a standard mood question:

Pick the response that describes how you felt today:

- ○ Worst ever
- ○ Bad mood
- ○ Average
- ○ Good mood
- ○ Best ever

along with a short (three to five item) AI-specific questionnaire (http://www.doi.org/10.7303/syn26067678.1). They were also prompted to journal on an AI-specific or general topic on one of those days. On the seventh day, participants were asked to complete a long survey related to their AI topic (Insomnia Severity Index (seven-item)[11], UCLA Loneliness Scale (three-item)[12], International Physical Activity Questionnaire (seven-item)[13,14], Behavioural Activation for Depression Scale[15] (BADS) for the sleep, social connections, body movement and positive activities AIs, respectively), as well as PHQ-9[9] and GAD-7[10] to get a deeper understanding of their mood (Figure 6.b.1).
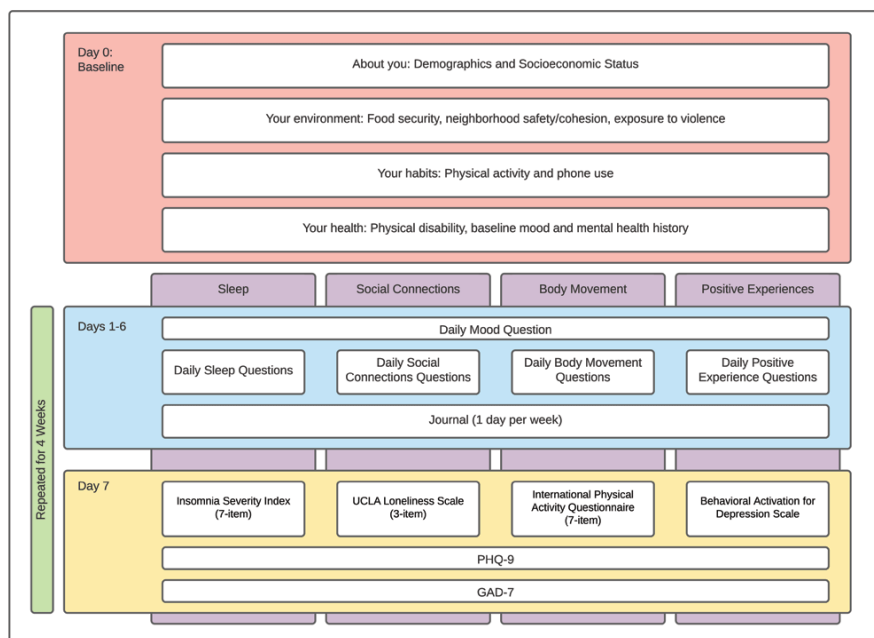
Figure 6.b.1: Baseline, daily and weekly survey design

Passive data collection

Participants could opt in to provide passive data collection about their phone activity and environment in order to understand their phone use habits. The statistics collected are daily screen time (a daily log of when the phone's screen is unlocked), charging time (a log of when the phone is connected to its charger), battery statistics (a log of battery charge throughout the day via the Android ACTION_BATTERY_CHANGED call), data usage (hourly reporting of amount of data transmitted and received), ambient light as measured by the phone's light sensor (sampled for ten seconds every five minutes in order to minimise battery consumption). No information was collected that could violate a participant's privacy, such as information about specific activities or apps used on the phone, call logs, or the content of messages. No identifiable location data was collected.

Learnings

Preliminary Testing

The data collection process was developed in collaboration with the professional youth advisors and youth advisory panels. We presented three different scenarios to the youth groups and incorporated their feedback into the design of the survey. We selected the survey cadence that was deemed the least burdensome. Youth groups also informed strategies to maximise engagement with surveys, such as reflection exercises and GIFs for performing surveys. These strategies have also been used successfully in other studies[16].

We timed the length of each survey type and found that on average daily surveys took no more than 5 minutes to complete in total, with a range of 30 secs to 5 minutes, with the weekly survey taking an average of 9 minutes, with a range of 3 to 22 minutes.

Survey Participation

In the UK, participants were likely to complete all the baseline surveys once they downloaded the study app (Table 6.a.1). This portion was slightly lower in South Africa and more so in India. Across all jurisdictions, the "Your Health" survey of physical health as well as current and historical mental health was completed the least. This could be because this survey was presented last in the menu of baseline surveys, but could also reflect the length and/or sensitivity of the subjects therein.

Table 6.a.1: Proportion completing the baseline surveys as a function of app participation (study enrollment)

	India	South Africa	UK
About You	1.0 (0.46)	1.0 (0.41)	1.0 (0.74)
Your Environment	0.88 (0.41)	0.93 (0.39)	0.97 (0.72)
Your Habits	0.87 (0.40)	0.92 (0.38)	0.97 (0.71)
Your Health	0.82 (0.38)	0.87 (0.36)	0.95 (0.70)

Participants active beyond week 1, typically completed slightly less than half of their daily (short) surveys throughout the week (6), and about half of them completed their long weekly survey. These numbers were relatively consistent across all jurisdictions and AIs (Table 6.a.2). Note that the Behavioural Activation for Depression Scale (Positive Experiences weekly survey) was substantially longer than the other AI weekly instruments (25 questions versus 3-7 questions for the Insomnia Severity Index, UCLA Loneliness Scale, International Physical Activity Questionnaire instruments).

Table 6.a.2: Average number (SD) of surveys in week 2 for participants active beyond week 1

	India		South Africa		UK	
	Daily (of 6)	Weekly (of 1)	Daily (of 6)	Weekly (of 1)	Daily (of 6)	Weekly (of 1)
Body Movement	2.28 (1.65)	0.5 (0.51)	2.45 (1.88)	0.53 (0.51)	2.56 (1.63)	0.54 (0.52)

Positive Experiences	2.59 (1.69)	0.52 (0.58)	1.81 (1.27)	0.52 (0.59)	2.2 (1.84)	0.34 (0.52)
Sleep	2.32 (1.6)	0.49 (0.61)	1.79 (1.27)	0.45 (0.51)	2.71 (1.73)	0.59 (0.56)
Social Connections	2.14 (1.76)	0.51 (0.51)	2.31 (1.51)	0.47 (0.53)	2.47 (1.66)	0.5 (0.54)

Participant Feedback

The last week of the study consisted of a remote user survey to determine what aspects of the experiment were burdensome, which engagement strategies were deemed helpful in motivating youth to complete the survey and ideas from youth to improve the survey experience. A similar survey is also administered when a participant asks to leave the study or has not completed a survey after 2 weeks. This information can be used to improve the survey experience.

A very small number of participants completed the withdrawal survey. Of those, 2 indicated they no longer had the time to participate. The remaining participants specified 'Other' as the reason for withdrawal. None indicated that the surveys asked too many questions, nor that they had concerns about privacy or the questions being too personal.

Those reaching the final week of the study were asked several questions about their experience in the study (Table 6.b.3). On average, most participants found answering questions every day to be difficult, but helpful. Though some participants indicated that the surveys were sometimes onerous and/or repetitive (Section 6.e "Final week feedback"). Thus, further work could spend more time optimising the data collection protocol for user experience.

Table 6.b.3: Final week survey results

About this study, looking back over these 12 weeks, how hard was it to answer questions every day?						
	Very Easy (0)	Easy (1)	Neutral (2)	Hard (3)	Very Hard (4)	Mean
	7	23	33	48	15	2.33

How helpful was it for you to reflect on your mood?						
	Very Un-helpful (0)	Un-helpful (1)	Neutral (2)	Helpful (3)	Very Helpful (4)	Mean
	1	5	46	58	17	2.67

Over the weeks, we gave you information about your mood and activities from the previous week, as well as occasional tips and fun facts about mood. **How engaging did you find these insights to be?**						
	Very un-engaging (0)	Un-engaging (1)	Neutral (2)	Engaging (3)	Very Engaging (4)	Mean
	1	15	42	44	16	2.5

What did you think about the GIFs we sent you at the end of the week?						
GIFs? What GIFs? (0)	Very un-engaging (1)	Un-engaging (2)	Neutral (3)	Engaging (4)	Very Engaging (5)	
17	2	3	21	30	30	3.31

Recommendations

While the survey instruments were typically well tolerated, future work can be done to refine the study protocol, AIs and survey instruments. In particular, a shorter version or alternative for the Positive Experiences weekly instrument (the Behavioural Activation for Depression Scale), which was substantially longer than all other AI weekly instruments, should be considered.

c. Recruitment

Approach

The quantitative arm of the MindKind project aimed to recruit 1500 youth participants for the MinKind study app from each of the 3 sites (India, South Africa, and UK). Inclusion criteria were:

- Participants should be between the ages of 18 and 24 years (16-24 in the UK)
- Participants should own an Android smartphone
- Participants should be conversant with English

Each site employed its own recruitment strategy and materials.

Prior to recruitment commencing team members from all sites attended fortnightly meetings to discuss approaches which could be uniform across all sites. Firstly, the common approach across all sites involved the inclusion of the youth advisory panels. Panel members were requested to design advertising and promoting materials. During the active recruitment phase, they were also called on to share these recruitment materials with their social networks and peers. Online strategies overall included social media posts, emailing colleges, university students groups, partner and youth organisations. However, the implementation of some of the recruitment approaches across all sites was also distinct. For example, school and university vacations during recruitment meant that some sites had much more success with certain online and offline strategies which are reported in this section below.

India

The recruitment commenced on 14 November 2021. The site team (PYA, Researchers, Communications Lead) met bi-weekly to discuss and review the recruitment strategy and implementation plan from September 2021 to February 2022. The aim was to create engaging content for youth to ensure the required enrolment. In order to be equitable and representative in our sample, both offline and online recruitment strategies were implemented. The site team used the following recruitment methods:

Recruitment Strategies

Consultation with the YPAG

The PYA engaged with the YPAG members over two sessions (approximately two hours) to review and comment on the team's recruitment strategies. The PYA conducted network mapping exercises to identify potential sources of dissemination, followed by individual check-in sessions to assist with implementation of the recruitment strategy. Apart from disseminating study information in their networks, six YPAG members also volunteered to be a part of the video series for social media.

Social Media

Social media was the primary pathway for recruitment. The team used Instagram, LinkedIn, Twitter, and Facebook. A set of eight videos and six posters were created for different social media platforms. All the posters can be accessed in Appendix I.6.c.1, page 1.

Figure 6.c.1: Two examples of recruitment post images from India

To amplify the reach of these posts, the posts tagged relevant stakeholders such as the consortium members, YPAG, partner organisations, organisations working with youth, and youth advocates. The India site team members also posted from their individual accounts. In addition, the team tracked the number of views, likes, re-shares, and number of people signing up on the study app.

Instagram:

Based on a promising response from Instagram, from January 2022, the team decided to move towards paid promotion of the posts to increase reach that would hopefully lead to increased enrolment.

The posts were curated and targeted to young people between the ages of 18 to 24 years, residing in India, with interests in areas such as psychology, self-care, health & wellness, digital data, research, internet privacy, health habits, etc. These are pre-existing interest categories on Instagram and cannot be created by an advertiser.

The team started advertising one poster and one video in the first week to observe the pattern of responses. Different creative assets and formats (videos, posters) were used, and a broader range of interest categories were selected (the full list can be seen in Appendix I.6.c.1, page 2) to increase the targeted audience size and avoid fatigue from constant exposure to one post. The target audience was exposed to two videos and three posters over January to February 2022 on Instagram.

Facebook:

To reach the required enrolment number, the team also used paid promotions on Facebook to advertise two posters to a similar demographic as Instagram in February 2022.

LinkedIn and Twitter:

14 tweets and 3 LinkedIn posts were posted from the organisation's page to disseminate information about the study.

Emails

Emails with information on the study and the poster were sent to partner organisations, organisations working with youth and mental health, personal contacts of the site team, with a request to disseminate information about the study with young people in their networks. The email template can be found in Appendix I.6.c.1, page 2.

Educational Institutes

20 educational institutes were contacted using emails, posters, and text-based services. Emails were sent to approximately 50 college administrators, professors, and other members of the staff with a request to share it within their student network. Emails were also sent to 1000 students of an educational institution. Student groups and representatives in educational institutions were contacted through phone calls. The team organised an online talk at one of the educational institutes attended by 48 students. Printed copies of posters were put up in five educational institutes with a QR code to scan and sign up for the study.

Collaboration with media organisation

In December 2021, the team consulted a youth-based for-profit media organisation to disseminate information on the study. To leverage their social media expertise and reach (with 298,000 followers on Instagram), seven stories and one reel was created and shared. The media organisation shared material with their networks via WhatsApp to 100 groups, and emails to 10,000 young people.

South Africa

The youth advisory panel was consulted on a range of components of the recruitment process. As they had already given feedback in the development stage of the App, they had a good awareness of the issues. The South African team's recruitment commenced on the 26th September 2021.

Recruitment strategies

South Africa used various approaches in the recruitment process. They were bulk SMS, emails, approaches to university and college institutions, community awareness and social media pages.

- *Emailing*
  This was the first method of recruitment whereby we obtained emails of potential participants and then we invited them to take part in the study. Emails were obtained from Higher Health's database of peer educators and COVID-19 volunteers. Additional email access was obtained from Walter Sisulu University by using the

central bulk email system as well as departmental databases as authorised by associated department heads.

- *Bulk SMS*

  After the use of emailing failed to yield the desired level of recruitment, the team had to make use also of bulk SMS as a way of recruiting more participants. The phone numbers were also obtained from Higher Health's database.

- *Community awareness*

  In a bid to raise awareness about the project so that more youth can participate. The South African team approached the community radio UCR that is situated in the university premises. The team had an opportunity to have a slot on the radio for 30 minutes during which they had a chance to explain more about the study and posters that they had posted on various social media pages. Thus, the team was given an opportunity to raise awareness and also to be able to advertise the project. Apart from that the team also requested for opening billboards, advertisements and live on-air announcements as a way of raising awareness. This assisted raising the numbers of participants because they were now convinced that this was a legitimate project taking place.

- *Social media pages*

  Social media played a significant role in raising awareness and also recruitment. The team approached the university's department of Marketing, Communication, and Development to assist the project team by uploading the flyers on the university Facebook page. Apart from Facebook the team also used their personal social media to raise awareness such as WhatsApp and Twitter. This also played a role in raising awareness of the project and recruitment.

Recruitment of Peer-educators

These are young people at higher institutions of learning who volunteer and are trained to provide information and counselling to their peers on health matters. The one source of these are from Higher Health which has nearly a thousand educators on their books. The other source is the Walter Sisulu University peer educators. We sent emails and SMS messages to all these individuals, inviting them to participate in the study.

Allied organisations

A number of non-governmental and non-profit organisations involved in youth networks, youth development and empowerment were identified. They were contacted to request their help in recruiting for the project. The following organisations were emailed:
- Activate Change Drivers Network ZA
- Hope for Africa
- Hope for Girl Child Network
- University of Johannesburg Institutional Office for HIV and AIDS (IOHA)
- Afrika Tikkun (YES Youth Programme)
- Swim for change

One important stakeholder was the Hope for Africa foundation which was on a tour to various municipalities around the country to engage the youth on the different opportunities,

resources, and services available to them. Our PYA joined in on the initiative representing the study and ensuring that participants could register onto the study successfully. The South Africa PYA joined a road trip in Newcastle on the 22nd November 2021 and had activations and radio station interviews; she was able to speak at the Nqubeko community radio station in Ladysmith KwaZulu-Natal about the study.

We were invited to speak at the WomenNow! Summit in Durban on the 4th December 2021 on mental health and specifically on the MindKind study in-order to create an awareness. A web app system for sending SMSs was used to reach out to the peer volunteers from Higher Health.

Recruitment Material

Posters and messages were developed with the assistance of the Youth Panel Group. Twenty posters were printed and distributed at relevant TVET colleges, while the same poster was used for online recruitment. This poster has a hyperlink to the MindKind project website (https://mindkindstudy.org/) for more information. Additional recruitment material is available in Appendix I.6.c.2.

Figure 6.c.2: Recruitment poster from South Africa

Mobile data remuneration

There was a realisation that data connectivity would be a significant determinant of engagement as phone data in South Africa is expensive. The recruitment process was thus done in such a way as to present the solution to this challenge. Data remuneration in the amount of R150 per month was used to mitigate against the potential hesitancy that could otherwise have acted as an obstacle to successful engagement and retention.

United Kingdom

Recruitment in the UK commenced on the 9th of August 2021. In anticipation of this date, several strategy meetings were held with the international MindKind team as well as within the UK to develop our recruitment strategy and advertising materials. During these meetings, the plan to recruit 1500 16–24-year-olds was discussed. Alongside this, the youth advisory panel was consulted on a range of components of the recruitment process; they had already given feedback in the development stage of the App and so had a good awareness of the issues.

Online strategies

Advertising on social media

The online recruitment campaign included social media advertisements, with advertisements targeted towards young people and parents, and online posters/social media posts with links to the study. The social media advertisements were linked to accounts created on both Facebook (which includes the Instagram app when placing ads) and Reddit , where advertisements are posted regularly. The study was also advertised on Oxford and Cambridge websites, and organisations such as the Black, African and Asian Therapy Network and the People in research network websites posting our study on both their website and newsletter. See Appendix I.6.c.3 for recruitment materials including links and posters (figures 1 and 2), see also insights from twitter posts provided in table 3 on page 5 of Appendix I.6.c.3.

We found that creating advertisements which related to current events was more successful in persuading young people to click and consider participating in the study (see Appendix I.6.c.3). Our most successful advertisements were based on creating new year's resolutions to track and improve mental health. We had more success with advertising which focused on potential insights into mental health provided by the research, as compared with advertisements focusing on data practices per se.

Direct emails

Targeted emails have been sent to educational institutions and third sector organisations working with people aged 16-24 years. These included secondary schools, youth groups, university student unions, university and college tutorial offices, and a range of charities. The numbers of emails sent are outlined in Table 1 in Appendix I.6.c.3.

Offline recruitment strategies

Our offline recruitment efforts included visiting colleges, universities and community centres to distribute posters and cards in person (see Appendix I.6.c.3). We shared the study to various universities to encourage students to participate in the study. Posters were also distributed and displayed at different universities in the country, particularly focusing on further and higher educational settings, trying to identify Android users. Posters and business cards with QR codes were distributed at a range of university departments, student unions and schools across England.

The table of potential participants who participated in the eligibility verification and registered an account on the enrollment website is shown in Table 1 in Appendix I.6.c.3, including those who eventually consented to participate in the study as well as those who did not. Across all countries women were recruited at a higher rate than expected based on baseline population demographics. Additionally, the overwhelming majority of those recruited reported lived experience of mental health challenges.

Table 6.c.1: Demographics and recruitment source of consented and unconsented registrants

	Consented			Unconsented		
Characteristic	India, N = 1,034[1]	South Africa, N = 932[1]	UK, N = 1,609[1]	India, N = 1,409[1]	South Africa, N = 710[1]	UK, N = 1,045[1]
Age						
16	0 (0%)	0 (0%)	349 (22%)	0 (0%)	0 (0%)	256 (24%)
17	0 (0%)	0 (0%)	424 (26%)	0 (0%)	0 (0%)	297 (28%)
18	178 (17%)	87 (9.3%)	129 (8.0%)	218 (15%)	61 (8.6%)	91 (8.7%)
19	163 (16%)	117 (13%)	135 (8.4%)	210 (15%)	87 (12%)	80 (7.7%)
20	158 (15%)	146 (16%)	142 (8.8%)	239 (17%)	102 (14%)	78 (7.5%)
21	166 (16%)	179 (19%)	114 (7.1%)	203 (14%)	116 (16%)	65 (6.2%)
22	134 (13%)	153 (16%)	106 (6.6%)	212 (15%)	113 (16%)	62 (5.9%)
23	125 (12%)	134 (14%)	108 (6.7%)	183 (13%)	119 (17%)	65 (6.2%)
24	110 (11%)	116 (12%)	102 (6.3%)	144 (10%)	112 (16%)	51 (4.9%)
Gender						
Woman	897 (87%)	737 (79%)	1,031 (64%)	1,270 (90%)	578 (81%)	652 (62%)
Man	103 (10.0%)	162 (17%)	247 (15%)	102 (7.2%)	104 (15%)	219 (21%)
Transgender/Nonbinary/Multiple/Other	21 (2.0%)	23 (2.5%)	296 (18%)	16 (1.1%)	18 (2.5%)	153 (15%)
Prefer not to say	13 (1.3%)	10 (1.1%)	35 (2.2%)	21 (1.5%)	10 (1.4%)	21 (2.0%)
Lived Experience						
Lived Experience	908 (88%)	623 (67%)	1,469 (91%)	1,188 (84%)	446 (63%)	921 (88%)
No Lived Experience	126 (12%)	309 (33%)	140 (8.7%)	221 (16%)	264 (37%)	124 (12%)
How did you hear about the study?						
Health clinic contact	0 (0%)	8 (0.9%)	0 (0%)	3 (0.2%)	4 (0.6%)	0 (0%)
Other	35 (3.4%)	17 (1.8%)	11 (0.7%)	33 (2.3%)	24 (3.4%)	9 (0.9%)
Paper flyer	0 (0%)	2 (0.2%)	5 (0.3%)	0 (0%)	0 (0%)	2 (0.2%)
Prefer not to say	9 (0.9%)	3 (0.3%)	4 (0.2%)	8 (0.6%)	2 (0.3%)	1 (<0.1%)
Referred by a friend	84 (8.1%)	79 (8.5%)	30 (1.9%)	88 (6.2%)	48 (6.8%)	9 (0.9%)
School or University contact	72 (7.0%)	204 (22%)	106 (6.6%)	72 (5.1%)	109 (15%)	54 (5.2%)
Social media advertisement	828 (80%)	606 (65%)	1,445 (90%)	1,198 (85%)	511 (72%)	965 (92%)
Web browser search	6 (0.6%)	13 (1.4%)	8 (0.5%)	7 (0.5%)	12 (1.7%)	5 (0.5%)

[1] n (%)

India Learnings

Social Media

Paid promotion on Instagram was the most effective strategy for recruitment. 883 out of 1037 youth were recruited after the promotions started on 17 January 2022 till 28 February 2022. Tracking engagement with the posts helped to design the communication strategy. For instance, the team learned that the videos were viewed by more men than women, however, that did not translate to increased enrolment. Women engaged more with poster content than the videos that also translated in increased enrolments. The team therefore decided to

expose content to more women than men. Please see Appendix I.6.c.1 (page 3) for detailed insights on paid promotions. The team observed that Instagram was more contemporary, appealed to a younger audience and led to better engagement rate than other platforms. While Facebook allowed for a more targeted reach (for e.g., reaching out to young people who only spoke English, used Android devices, etc.), this did not translate to increased enrolments. The team observed clicks on the sign-up button, but very few proceeded to sign-up for the study (see Appendix I.6.c.1, page 3).

Unpaid posts on Twitter and LinkedIn yielded low engagement from youth compared to Instagram (see Appendix I.6.c.1, page 4). Thus, paid promotions were not used for those platforms.

Involving and engaging the communications lead within the organisation, with prior experience in using social media was valuable and helped India site recruit effectively in the short timeline. In-house assistance of a graphic designer aided the implementation plan.

Emails

Emails did not prove to be an effective strategy; the team received less than five responses out of the 100 emails sent. Emailing personal contacts garnered more responses than emailing non-personal contacts.

Educational Institutes

The response rate from the posters, text messages, and individual check-in with students at educational institutes was very low. Institute staff and students reported feeling overburdened with online classes. Out of the five institutes contacted, only one had an active student group who shared the recruitment material. However, this did not lead to increased enrolments.

Collaboration with media organisation

Collaboration with the media organisation did not lead to increased enrolments. The team presumes the large following on their Instagram page did not engage with research material as much as other topics that were not related to mental health. The organisation's feedback was that there were too many steps involved to enrol in the study which reduced the enrolments. The quality of the posts and collaterals were not as engaging compared to other promoted content on their page.

Technical challenges

Due to a technical malfunction in the MindKind study app, 139 participants were not able to enrol for the study in the first month of recruitment. The participants were unable to receive the one-time password to enrol on the study app. The site team tried to encourage the participants to sign up again, once the malfunction was resolved. However, the enrollment rate was very low.

South Africa Learnings

- There were challenges in recruiting people using their personal information such as phone numbers and emails. This was due to the increase in scams that were happening and this led to many people to be more conscious of whom to give their information and who has access to it.
- Many youth are sceptical of new technologies or apps and new programs. A lot of awareness was needed during recruitment so that we could convince them that this was a legitimate project that would be helpful for mental wellbeing.
- The structure of the message meant that the participants needed to be more informed, such that the participants would not be left with doubts or questions with regards to what the project entailed.
- Challenges for the South African site were connectivity and payment for data where participants were not able to access free wi-fi. Some of the participants and research team members were from relatively remote or rural areas which affected connectivity. Payment for data was essential for the recruitment and ongoing participation of subjects. However, a relatively small proportion of participants (186 of 932) requested data reimbursement.

UK Learnings

Operating system

Even though retention of app users remains high in the UK (34%), a major barrier to the UK recruitment was the predominance of the Apple/ iOS system in the eligible age-group. Although surveys indicate that Android smartphone users comprise over 70% of the smartphone global market share, this is markedly lower for young people[17] living in higher-resource settings. Some data from the UK indicates that almost half of smartphone users are on Android phones, but this is less in younger age-groups. At our UK in-person events approximately 10% of young people approached were Android users. The YPAG were themselves unable to recruit friends and contacts to the study because of the operating system and so this has been a pervasive difficulty.

Advertisements

Our advertisements were updated regularly to ensure that many potentially eligible participants saw them and that those who are interested in participating have easily digestible information. The YPAG suggestion of keeping content succinct was in line with popular platforms offering brief videos. Trends are also important for visibility, and using the right hashtag (for example #mentalhealth, #mentalhealthawareness, #datasharing) was crucial to ensure those following 'mental health' posts would be able to see our recruitment posts. The social media advertisements were most effective at certain times, for example advertisements discussing new year's resolutions over Christmas break and targeting who were having to self-isolate during peaks of the COVID-19 pandemic. Clicks on the advertisements were further increased twofold as a result of 3 advertisements running simultaneously, see insights from paid promotions provided in table 2 on page 5 of Appendix I.6.c.3.

Age Groups

The UK site was the only one recruiting 16-17 year olds, and this age group represents the largest age group (~50% of the participants registering). Despite emailing several schools and colleges across the country, most participants who fell within the 16-17 year age groups joined the study following links on social media. Within the email sent to schools and colleges, the responsible staff member was encouraged to share the study details and joining link in class or put up posters across their campuses with the most visibility to their students. However, the offline strategy of putting up posters in schools and colleges appears to be the least effective approach when recruiting this age group. This is similar to the older participants, which further emphasises the direct impact of recruiting participants via social media advertisements.

Table 6.c.2: Recruitment source by age group for UK enrollees.

Characteristic	16, N = 339[1]	17, N = 415[1]	18, N = 129[1]	19, N = 134[1]	20, N = 140[1]	21, N = 112[1]	22, N = 104[1]	23, N = 108[1]	24, N = 101[1]
How did you hear about the study?									
Other	1 (0.3%)	3 (0.7%)	1 (0.8%)	0 (0%)	1 (0.7%)	0 (0%)	4 (3.8%)	0 (0%)	0 (0%)
Paper flyer	0 (0%)	0 (0%)	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)	2 (1.9%)	0 (0%)	2 (2.0%)
Prefer not to say	1 (0.3%)	0 (0%)	1 (0.8%)	1 (0.7%)	0 (0%)	1 (0.9%)	0 (0%)	0 (0%)	0 (0%)
Referred by a friend	2 (0.6%)	5 (1.2%)	7 (5.4%)	6 (4.5%)	3 (2.1%)	0 (0%)	1 (1.0%)	4 (3.7%)	2 (2.0%)
School or University contact	15 (4.4%)	22 (5.3%)	27 (21%)	9 (6.7%)	12 (8.6%)	11 (9.8%)	8 (7.7%)	0 (0%)	0 (0%)
Social media advertisement	320 (94%)	384 (93%)	89 (69%)	117 (87%)	124 (89%)	99 (88%)	88 (85%)	103 (95%)	97 (96%)
Web browser search	0 (0%)	1 (0.2%)	3 (2.3%)	1 (0.7%)	0 (0%)	1 (0.9%)	1 (1.0%)	1 (0.9%)	0 (0%)

[1] n (%)

Recommendations

India Recommendations

Recruiting a communications lead with prior experience and expertise to engage with youth on digital platforms will be helpful in the future.

Co-designing the recruitment material with the YPAG members prior to recruitment was very helpful.

Given the delays in recruitment, in hindsight, the team could have explored paid promotion posts on social media earlier. Prior discussions within the consortium on our stand on paid posts, and on issues such as using paid communications and marketing teams or social media youth 'influencers' could have eased the process of planning. However, sharing learning from across sites was helpful and could be done in the future.

It might help to have both Android and iOS users in the future as it taps into diverse youth demographics.

Allocating sufficient time for pre-testing the study app to avoid technical malfunctions would have been helpful.

South Africa Recommendations

The use of social media in raising awareness proved to be more effective in the recruitment of participants although in most cases, some were worried that it might be a scam when they received an email or sms. Raising awareness helps to dispute the issues of scam amongst the potential participants. Amongst the social media platform facebook proved to be more effective unlike other media. This may have been due to most youths being more active on facebook.

A recruitment goal of 1500 requires more time and various ways of recruitment especially when using online recruitment. Due to scams many people no longer take online advertisements seriously hence more effort has to be put on ways of recruiting participants.

Raising awareness should happen before their recruitment process commences as this will give the youths the opportunity to know about the project. When recruitment starts it will be easy for youths to take part as they will have full information concerning the project.

For people without access to wi-fi, and who cannot financially afford to join the study due to the expense of buying mobile phone data, it is essential to provide sufficient phone data for their participation. The amount to be provided needs to be based on a scientific calculation of the actual cost of participation i.e. how much data would be required for participation and how much this data would cost. The data can either be loaded onto peoples' phones or another mechanism must be found to pay a sufficient amount to cover the cost, for example into a bank account. This can potentially raise ethical issues around confidentiality, but it would (a) be more unethical to put added financial burden on already poor people and (b) many people would simply not participate without some assistance to do so. As participation may at times take longer than anticipated for example due to time taken becoming familiar with the app or difficulties navigating the app, it is preferable to pay more than the exact calculated amount. People's participation should never leave them financially compromised and hence potentially unable to buy essentials such as food or communicate with family, because their mobile data is being used up by their participation. In this pilot study, the process for requesting data reimbursement was manual. In the future, a more streamlined way to provide reimbursement would be ideal.

UK Recommendations

A major learning for the UK when recruiting 16-24 year olds was that social media is the most effective online strategy to approach this sample. However, the type of social media platform itself is also crucial. From the analytical reports produced during the recruitment phase, a significantly large number of participants joined following the link to participate via Instagram. As a popular social media platform, the recruitment materials produced were targeted to popular trends during that phase. For example, the posters were suited to the New Year's theme. This level of outreach relies on knowledge of marketing strategies often used by popular retail sites to attract the attention of its targeted audience. Setting targeted advertisements meant the materials had to be relevant for the set audience, i.e., bright pictures with prominent headlines in these posters. Therefore, understanding the efficient way to use these platforms requires having close discussions with the platforms' marketing team (Meta's marketing team in this case). The advertisement engagement analytical figures provided by Meta also allows for the best posters to be highlighted. However, when placing

the advert, the cost of these should also be accounted for in the budget, with each advertisement costing a certain amount set for each click. Generally, keeping track of trends is also important when posting on social media platforms. These trends are often linked to popular hashtags that emerge during the week or even during the day.

d. Enrollment

Approach

Data from consented and unconsented participants who passed the eligibility quiz and registered their phone number to begin the consent process were analysed to assess questions preference and acceptability of governance models.

Participant preference was assessed by quantifying the selections from the two questions ('How should researchers be allowed to access the study data' and 'Who controls access to the data'?) in the study enrollees randomised to Option A (Figure 6.a.1). Only participants who consented to join the study were included. A Chi-square test was used to assess departures from equal probability were performed globally and within-country. Confidence intervals were generated based on a multinomial distribution. A multinomial regression model was used to assess the effect of age, gender, country and reported history of lived experience of mental health challenges.

Acceptability of governance models was assessed by comparing the rate of enrollment of participants randomised to Options B-D (Figure 6.a.1). Logistic regression was used to assess the effect of governance model (Option). Analyses were performed both within- and across-country (adjusting for country). Additional models included terms for age, gender and reported history of lived experience of mental health challenges.

We also quantified the voting preferences of enrollees who were either randomised to a democratic model (Options C and D) or selected the democratic model when given the choice (Option A). For prospective participants who did not consent, we examined the rate of drop off through the individual screens of the informed e-consent process to understand at which portions of the consent were associated with drop-off.

Learnings

Participant Preference

Participants in *Group A: Participant Choice* strongly preferred Secure Server when given a choice about how researchers access their data (Chi-squared *p*-val < < 2.2e-16). This was true across sites ($\hat{p}$(Secure Server) = 0.56, 0.47, 0.53, for India, South Africa and UK, respectively) (Figure 6.d.1). There was also no statistically significant difference by age, gender or Lived Experience.
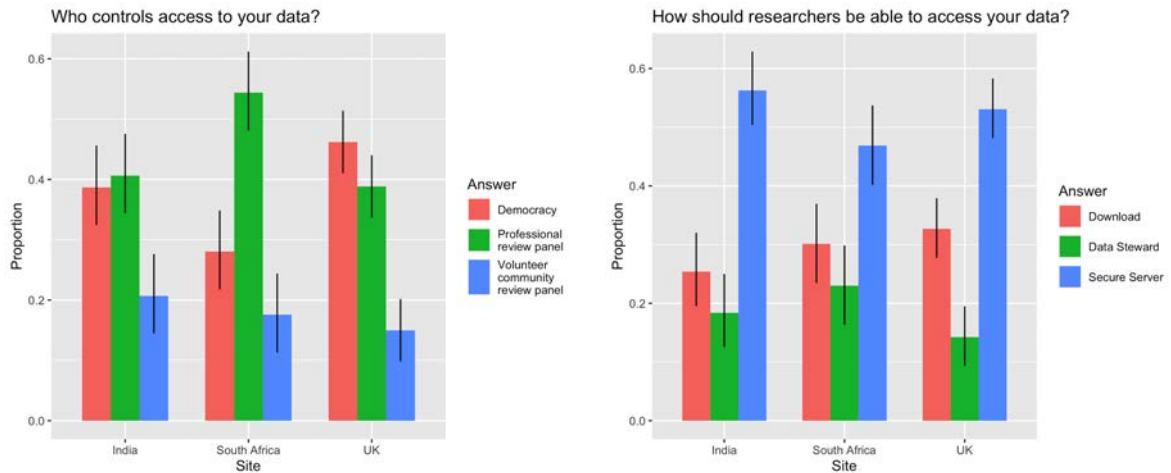
Figure 6.d.1: Participant choice for "*Who controls access to your data?*" and "*How should researchers access your data?*" for participants randomised to Group A.

When given a choice about who controls access to the data, participants in India and UK showed a preference for Democracy or Professional Review Panel over Volunteer Review Panel (*p*-value = 9.499e-05 and 7.843e-15 for India and UK, respectively) (Figure 6.d.1). However, there was no statistically significant difference between Democracy and Professional Review Panel in either country (India 95% CI for Democracy = (0.32, 0.46) and for Prof. Review = (0.34, 0.48); UK 95% CI for Democracy = (0.41, 0.51) and for Prof. Review = (0.34, 0.44)). In contrast, South Africa showed a strong preference for Professional Review Panel ($\hat{p}$(Prof. Review) = 0.54, Chi-squared *p-value* = 6.168e-12) (Figure 6.d.1). There was a modest effect of age (*p-value* = 0.05 and 0.05 for Democracy and Volunteer Review Panel, respectively, relative to Professional Review Panel) (Figure 6.d.2). For all three countries, older participants were less likely to choose Professional Review than younger participants.
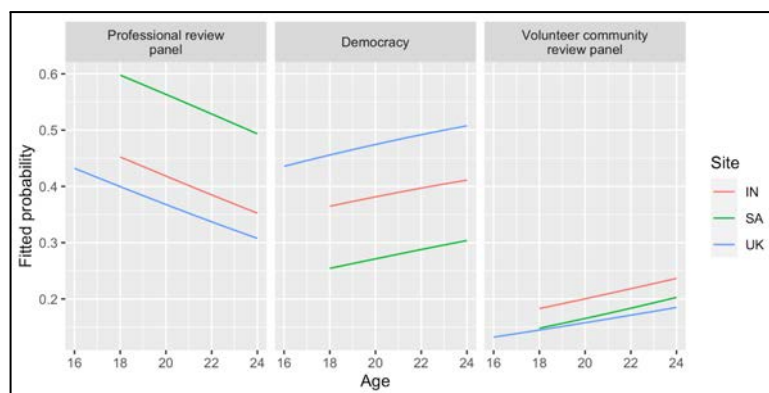
Figure 6.d.2: Age dependent preference for data access control.

Participant Acceptability

In addition to exploring what participants prefer, we also examined whether governance models affected participants' willingness to enrol in the MindKind Study. Enrollment between

the three "acceptability" arms was not statistically significantly different (p-value = 0.218) (Figure 6.d.3). This did not change by adding country, history of lived experience, age or gender to the model (p-value = 0.185) or analysing each country separately (p-value = 0.465, 0.627, and 0.056, for India, SA and UK, respectively). However, in UK only there was a modest increase in enrollment in Group D: Democracy + Server over Group B: Researcher Norms (unadjusted p-value = 0.022, OR = 1.29), though this would not survive multiple test corrections. In other words, though participants showed a preference for specific governance models, these models showed no significant improvement in study enrollment.

Enrollment rate also did not significantly change by age (p-value = 0.878) or gender (p-value = 0.095), though it did show statistically significant differences by country (p-value < 2.2e-16) and by history of lived experience (p-value = 0.0017). Notably, participants with history of lived experience were significantly more likely to enrol than participants who report no history (OR = 1.26).
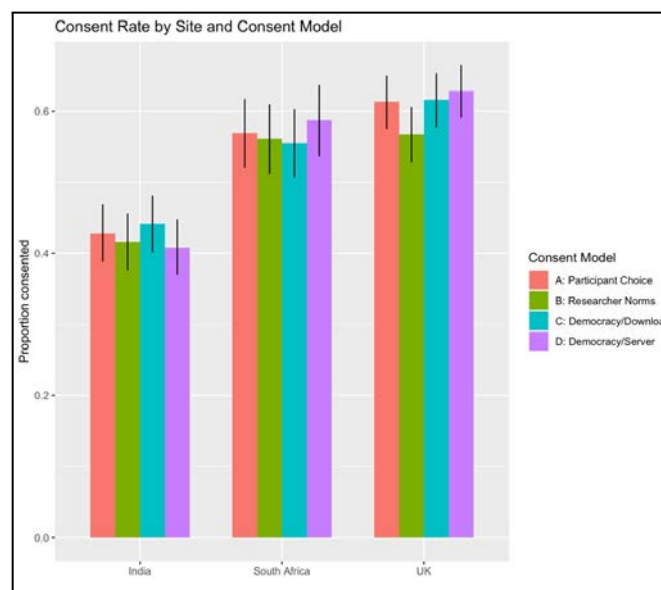
Figure 6.d.3: Consent rate by country and Consent Model

Democracy Choices

For those participants that chose or were randomised to Democratic determination of criteria for accessing data, we assessed the votes and, in most cases, found concordance across countries (Table 6.d.1). Participants from all countries preferred that their data not be used to make a profit, and that comercial companies should have to pay to use the data. They also agreed that results should be shared for free with the world and also in an easy-to-understand format for study participants. In contrast, there was disagreement about how the data can be used.

While participants from India and South Africa preferred that their data only be used for mental health research, participants from the UK showed a slight preference that their data be used for all types of health research.

Table 6.d.1: Results of democratic voting.

Question	India, N = 628[1]	South Africa, N = 529[1]	UK, N = 1,018[1]
Can my data be used by researchers to make a profit?			
Yes, my data can be used by researchers to make a profit.	187 (30%)	170 (32%)	109 (11%)
No, my data can NOT be used by researchers to make a profit.	353 (56%)	307 (58%)	610 (60%)
I don't care if my data is used by researchers to make a profit..	88 (14%)	52 (9.8%)	298 (29%)
Do people have to pay to use my data?			
Nobody should have to pay to use my data.	216 (34%)	190 (36%)	369 (36%)
Only commercial companies should have to pay to use my data.	365 (58%)	310 (59%)	468 (46%)
I don't care if people have to pay to use my data.	47 (7.5%)	29 (5.5%)	181 (18%)
How can my data be used?			
My data should be available for broad research purposes.	117 (19%)	77 (15%)	213 (21%)
My data should be available for all types of health research.	160 (25%)	172 (33%)	397 (39%)
My data should only be available for mental health research.	320 (51%)	262 (50%)	307 (30%)
I don't care how my data is used.	31 (4.9%)	18 (3.4%)	101 (9.9%)
How can results be shared with participants?			
Results should be shared for free with the world.	57 (9.1%)	65 (12%)	98 (9.6%)
Results should be shared in an easy to understand way with participants.	206 (33%)	215 (41%)	265 (26%)
Both are important to me.	352 (56%)	242 (46%)	592 (58%)
I don't care how results are shared with participants.	13 (2.1%)	7 (1.3%)	63 (6.2%)

[1] n (%)

Enrollment Drop Off

Post-registration enrollment rates varied by country (42.3%, 56.8% and 60.6% for India, South Africa and UK, respectively). We also observe different drop-off patterns by country and history of lived experience (Figs 6.d.5-9). Overall, we see the highest drop-off on the first page of the informed consent (Study Summary), with notable bumps at the start of the other section breaks (About Data Sharing and Summary and Signature) (Figure 6.e.4). This implies that while the menu breaks are designed to provide guide-posts in the consent procedure, practically speaking they provide break-points that encourage drop-off.

We also observe a notable portion (10.3%) of drop-off occuring on the consent signature page. Other lesser drop-off peaks occur on the page

detailing the Risks and Benefits, as well as the quiz question or governance choices. Since these are designed to inform participants and reinforce learning,
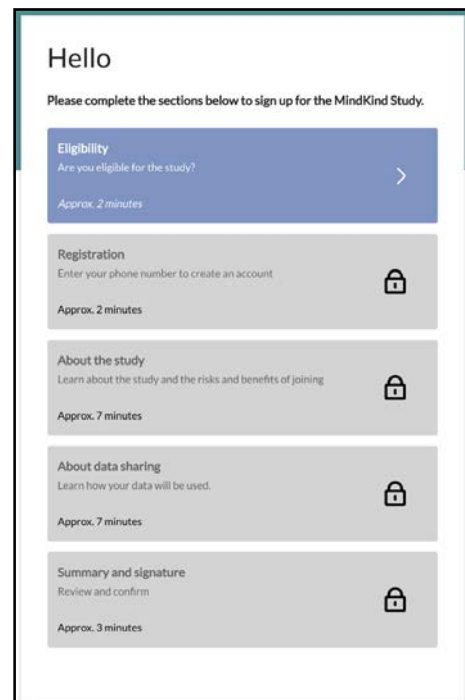
Figure 6.d.4: Consent flow menu

these are natural places for potential participants to consider their comfort in participating. On the other hand, the six democracy voting pages were not a large contributor to drop off (4.5% of drop-off in the Democracy + Download and Democracy + Server arms).
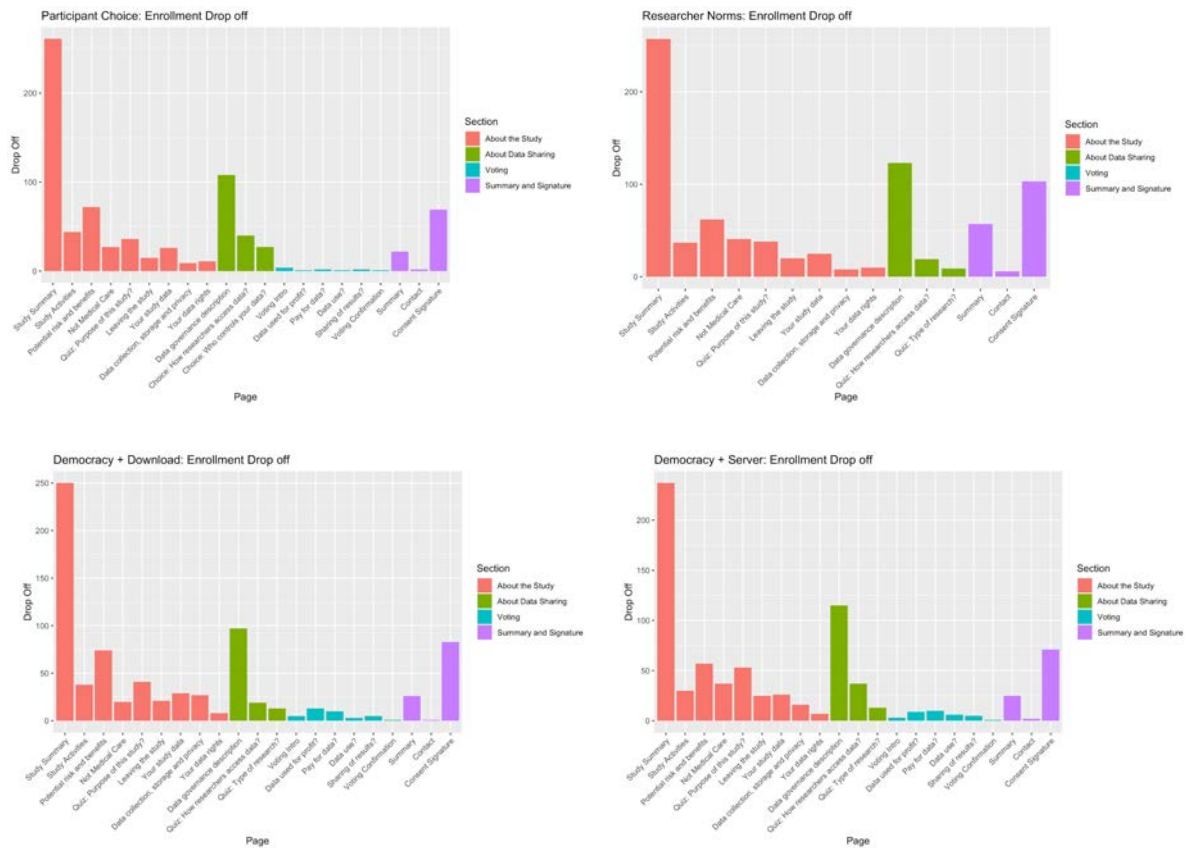
Figure 6.d.5: Participant drop-off by consent model across all countries. Consent model differences occur in the "About Data Sharing" (green). Voting occurs for participants in the Democracy + Download (Group C) and Democracy + Server (Group D) models, as well as for those participants in Group A (Participant Choice) opting for democratic vote.

Despite these general trends, we observe differences in patterns across countries. In particular, in South Africa more than 50% of prospective participants drop off immediately, on the first page of the informed consent. In contrast, in India participant drop-off is much more evenly distributed throughout the informed consent. Behaviour in the UK appears to be somewhere between those two extremes.

Recommendations

Study Feasibility

This pilot study suggests that remote (digital) studies of mental health will contain multiple sources of bias. In particular, the experiences of men will be underrepresented, as well as those without reported history of Lived Experience. There are likely to be other sources of bias not examined here, including socioeconomic status, education and others. Therefore, any future studies will need to understand that caveat.

Informed Consent

While some sources of enrollment friction are desirable (e.g. quiz questions to reinforce learning), other sources of friction like section breaks may cause unnecessary drop-off. We recommend designing an informed consent procedure without menu/section breaks (e.g. those in Figure 6.d.4).
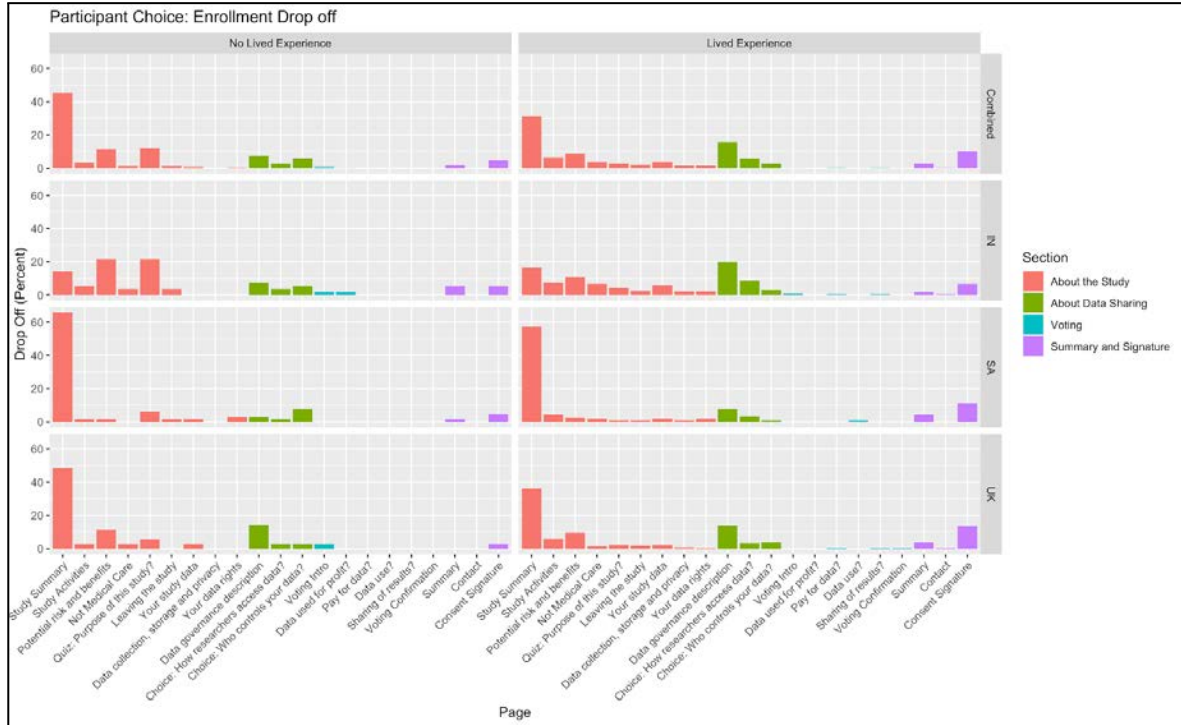
Figure 6.d.6: Participant drop-off by country and Lived Experience for Consent Model A.
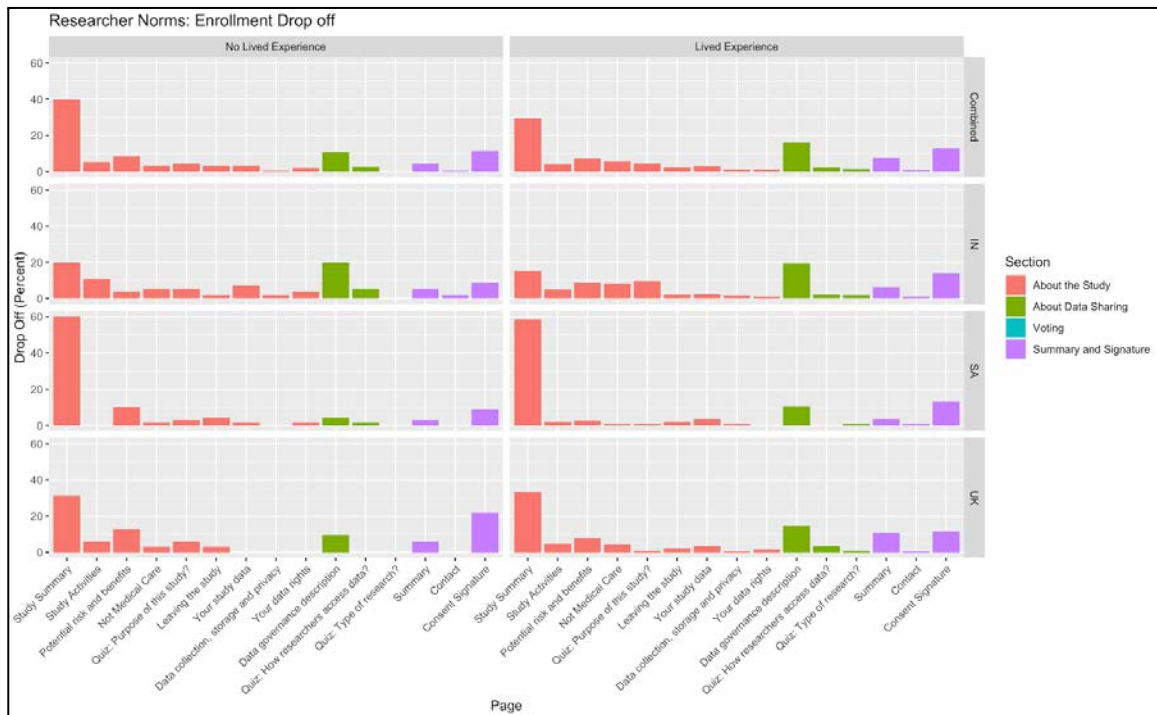
Figure 6.d.7: Participant drop-off by country and Lived Experience for Consent Model B.
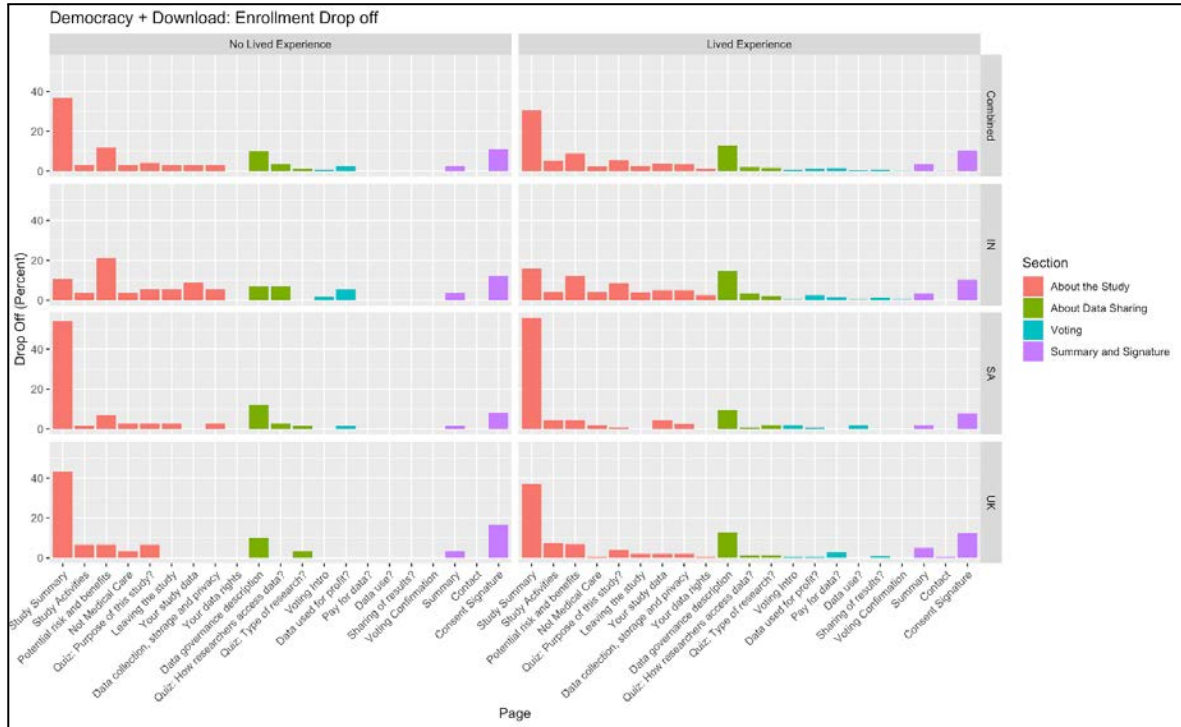
Figure 6.d.8: Participant drop-off by country and Lived Experience for Consent Model C.
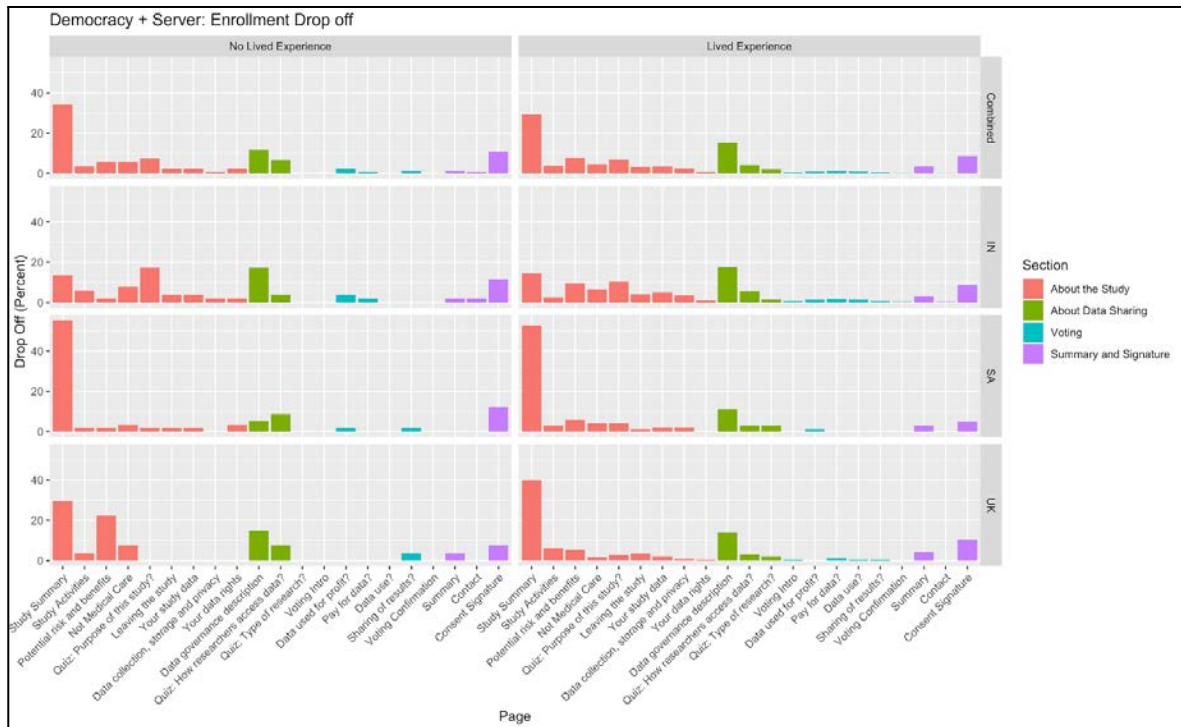
Figure 6.d.9: Participant drop-off by country and Lived Experience for Consent Model D.

e. Engagement/Retention

Approach

Upon enrollment into the study participants are directed to the Google Play Store to download the study app (Figure 7.a.1). They are first prompted to opt in to supply passive background recorder data. They are then directed to the main study screen which displays their available surveys. In order to proceed to the daily/weekly AI surveys (Figure 6.a.3), they must first complete the "About You" baseline demographic survey. Engagement and retention is measured relative to the completion of this survey in multiple ways:

(1) *App engagement* is measured as the proportion of consented participants who complete the "About You" baseline survey.
(2) *App retention* is measured by the elapsed time between the completion of the "About You" survey and the last survey completion date.
(3) *Survey engagement* is measured by the number of surveys completed.
(4) *Passive data engagement* is measured by the proportion of participants contributing background recorder data, and duration of contribution.

Upon enrollment, participants are randomised into one of two engagement arms (Figure 6.a.2). Participants in Arm 1 choose the AI topic of focus for each of their three 4-week rotations. Participants in Arm 2 are randomly assigned AI topics. We specifically test the effect of Engagement Arm on *app retention* and *survey engagement*, as well as the effect of Consent Model. We also examine engagement and retention relative to selected/assigned AI.

Learnings

App Engagement

Of participants consenting to the study, the proportion downloading and interacting with the app (completion of the "About You" baseline survey) differed substantially by country (46%, 41% and 74% for India, South Africa and UK, respectively). Participants with Lived Experience were more likely than those without to engage with the app (p-value = 0.031), as well as participants in the Democracy/Server Access consent model (model D) relative to the Researcher Norms model (model B) (p-value = 0.034) (Table 6.e.1). Both of these associations appear to be driven by participants in India, and are not significant in South Africa or the UK. In the UK, we also observed a higher proportion of app engagement in the youngest age group (16-17, 76%) versus those 18 and older (71%). However, the inclusion of this younger age group did not drive the differences in app engagement observed between countries.

App Retention

In-app study retention also differed significantly by country with median (Interquartile range (IRQ)) = 2 (1,13), 6 (1, 41), 11 (2, 44) days for India, South Africa and UK, respectively (log-rank test for survival p-value < 1e-5) (Figure 6.e.1, Table 6.e.2). In context, a previous meta-analysis of mHealth studies in the US observed a median number of days of retention of 2 days for this age group[1].

Table 6.e.1: App engagement (logistic regression) model for each country as well as all countries combined.

Characteristic	All Countries			India			South Africa			UK		
	OR[1,2]	95% CI[2]	p-value	OR[1,2]	95% CI[2]	p-value	OR[1,2]	95% CI[2]	p-value	OR[1,2]	95% CI[2]	p-value
Country												
IN	—	—										
UK	3.09***	2.58, 3.70	<0.001									
SA	0.88	0.73, 1.06	0.2									
Consent Model												
B: Researcher Norms	—	—		—	—		—	—		—	—	
A: Participant Choice	1.18	0.97, 1.43	0.11	1.12	0.79, 1.61	0.5	1.14	0.79, 1.65	0.5	1.25	0.91, 1.72	0.2
C: Democracy/Download	1.16	0.95, 1.42	0.13	1.13	0.79, 1.60	0.5	1.17	0.81, 1.70	0.4	1.19	0.87, 1.64	0.3
D: Democracy/Server	1.24*	1.02, 1.51	0.034	1.63**	1.14, 2.32	0.007	1.17	0.80, 1.71	0.4	1.04	0.76, 1.41	0.8
Age	0.98	0.95, 1.01	0.2	0.99	0.93, 1.06	0.8	1.03	0.96, 1.10	0.5	0.96*	0.92, 1.00	0.043
Gender												
Woman	—	—		—	—		—	—		—	—	
Man	1.03	0.84, 1.26	0.8	1.13	0.74, 1.70	0.6	0.97	0.68, 1.37	0.9	0.95	0.69, 1.32	0.8
Transgender/Nonbinary/Multiple/Other	1.06	0.82, 1.39	0.7	0.88	0.35, 2.13	0.8	0.72	0.29, 1.69	0.5	1.13	0.83, 1.54	0.4
Prefer not to say	1.16	0.66, 2.09	0.6	1.78	0.59, 5.99	0.3	0.62	0.13, 2.25	0.5	1.20	0.56, 2.87	0.7
Lived Experience												
FALSE	—	—		—	—		—	—		—	—	
TRUE	1.24*	1.02, 1.51	0.031	1.83**	1.24, 2.75	0.003	1.20	0.91, 1.60	0.2	0.86	0.56, 1.29	0.5

[1] *p<0.05; **p<0.01; ***p<0.001
[2] OR = Odds Ratio, CI = Confidence Interval

This is also generally more than that observed in the uncompensated mental health study, Start (median = 2 days), however it is substantially shorter than the mental health study, Brighten, in which participants were compensated for their participation (median = 26 days)[1]. In the UK, the younger age group (16-17) were more likely to

stay in the study longer (median (IQR) = 14 (3, 55)) than those 18 or older (median (IQR) = 8 (2, 36)) (log-rank test for survival p-value = 0.002). However, both groups showed similar 12-week retention (95% confidence interval for probability of 12-week survival = (0.125, 0.183) and (0.099, 0.152) for the younger and older age groups, respectively).

Our primary hypothesis was that participants given a choice of study topic would show more engagement than those without a choice. While we observe a significant difference in retention by engagement arm, we actually find that Arm 2 (pre-assigned AI model) were retained longer in the study than those in Arm 1 (self-selected AI model) (log-rank test for survival p-value = 6.3e-4).
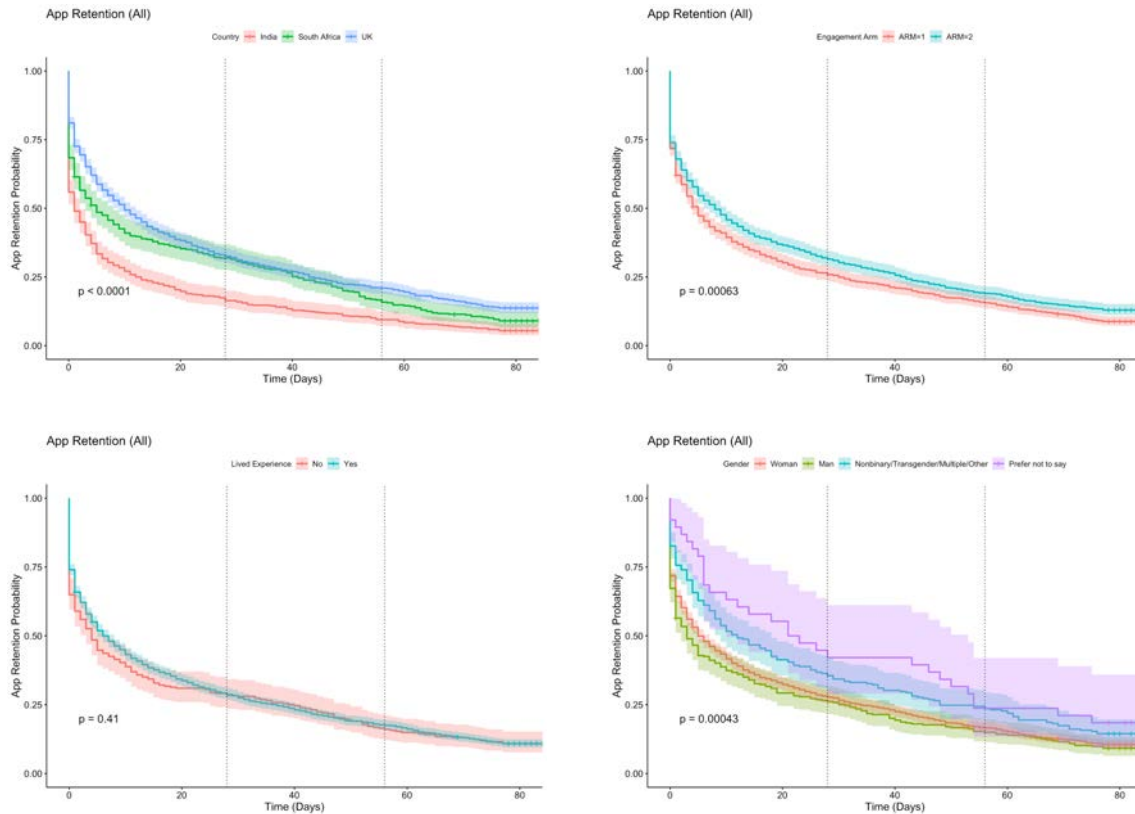
Figure 6.e.1: Survival curves for Country, Engagement Arm, Lived Experience and Gender

We also observed a significant effect of gender (log-rank test for survival p-value = 4.3e-4) with those identifying as transgender, nonbinary/third gender, other, selecting any combination of more than one gender as well as those not specifying their gender participating longer than those who selected 'women' or 'men' only. There was no statistically significant effect observed for the retention relative to Lived Experience (log-rank test for survival p-value = 0.41) or Consent Model (log-rank test for survival p-value = 0.87).

Table 6.e.2: Study retention probabilities for 2, 4, 8 and 12 weeks.

Characteristic	14 Days	28 Days	56 Days	84 Days	p-value[1]
Engagement Arm					<0.001
1	35% (32%, 38%)	26% (23%, 29%)	16% (14%, 18%)	8.8% (7.2%, 11%)	
2	41% (38%, 44%)	31% (29%, 34%)	19% (17%, 22%)	13% (11%, 15%)	
Consent Model					0.9
B: Researcher Norms	38% (34%, 43%)	27% (23%, 31%)	17% (14%, 21%)	10% (7.6%, 13%)	
A: Participant Choice	38% (34%, 43%)	31% (27%, 35%)	19% (16%, 22%)	11% (9.1%, 15%)	
C: Democracy/Download	38% (34%, 42%)	29% (25%, 33%)	17% (14%, 20%)	11% (8.5%, 14%)	
D: Democracy/Server	37% (33%, 42%)	28% (25%, 32%)	17% (14%, 21%)	11% (8.7%, 14%)	
Lived Experience					0.4
FALSE	34% (29%, 41%)	28% (23%, 34%)	16% (12%, 21%)	11% (7.7%, 15%)	
TRUE	38% (36%, 41%)	29% (27%, 31%)	17% (16%, 19%)	11% (9.5%, 12%)	
Gender					<0.001
Woman	37% (34%, 39%)	28% (26%, 30%)	17% (15%, 19%)	10% (9.0%, 12%)	
Man	34% (29%, 40%)	26% (22%, 32%)	15% (11%, 20%)	9.2% (6.4%, 13%)	
Transgender/Nonbinary/Multiple/Other	47% (41%, 53%)	36% (30%, 42%)	24% (19%, 30%)	14% (11%, 20%)	
Prefer not to say	58% (44%, 76%)	42% (29%, 61%)	24% (13%, 42%)	18% (9.4%, 36%)	
Country					<0.001
India	24% (20%, 28%)	16% (13%, 20%)	9.5% (7.2%, 12%)	5.5% (3.8%, 7.9%)	
South Africa	39% (34%, 44%)	32% (28%, 37%)	16% (13%, 20%)	9.0% (6.6%, 12%)	
UK	43% (41%, 46%)	33% (30%, 35%)	21% (19%, 23%)	14% (12%, 16%)	

[1] Log-rank test

Table 6.e.3: Cox regression model for Engagement Arm and Consent Model adjusted for Age, Gender, Lived Experience and Country.

Characteristic	HR[1,2]	95% CI[2]	p-value
Engagement Arm			
1	—	—	
2	0.82***	0.75, 0.90	<0.001
Consent Model			
B: Researcher Norms	—	—	
A: Participant Choice	0.93	0.81, 1.06	0.3
C: Democracy/Download	0.94	0.83, 1.08	0.4
D: Democracy/Server	0.95	0.83, 1.08	0.4
Age	1.02	0.99, 1.04	0.14

[1] *p<0.05; **p<0.01; ***p<0.001
[2] HR = Hazard Ratio, CI = Confidence Interval

We also performed Cox regression to verify these results, particularly the effect of Engagement Arm and Consent model, while adjusting for other variables (Age (adjusted), Gender (stratified), Lived Experience (stratified) and Country(stratified)) (Table 6.e.3). As with the univariate analysis we continue to observe statistically significantly increased retention in Arm 2 relative to Arm 1 (p-value < 0.001) and no statistically significant differences across Consent Model (ANOVA p-value = 0.84). The Engagement Arm effect is observed in both India (p-value = 0.014) and UK (p-value < 0.001), but not South Africa (p-value = 0.60). This may be due, in part, to the fact that South African participants received compensation for participation in contrast to participants in the other two countries.

Survey Engagement

Mirroring the App Retention results, we observed differences in the number of surveys completed by country, with median (IRQ) = 5 (4, 8), 6 (4, 14), and 8 (5, 16) for India, South Africa and the UK, respectively. The proportion of participants contributing at least 50% of the protocol surveys was 3.8%, 5.3% and 10.1% in India, South Africa and the UK, respectively.

The longer retention of younger participants (age 16-17) in the UK translated into only slightly higher survey engagement (median (IRQ) = 9 (5, 19) and 7 (5, 15) for the younger and older UK participants, respectively). The proportion of the younger participants completing 50% of the survey protocol was 11.1%.

Table 6.e.4: Model estimates for number of surveys completed, using a truncated negative binomial model with hurdle for completing more than the baseline surveys.

Characteristic	Zero Hurdle (Logisitic)			Counts Model (Neg Binomial)		
	OR[1,2]	SE[2]	p-value	IRR[1,2]	SE[2]	p-value
Country						
India	—	—		—	—	
South Africa	1.90***	0.151	<0.001	1.48*	0.155	0.011
UK	3.17***	0.131	<0.001	1.56***	0.129	<0.001
Engagement Arm						
1	—	—		—	—	
2	1.16	0.104	0.2	1.31**	0.090	0.003
Consent Model						
B: Researcher Norms	—	—		—	—	
A: Participant Choice	1.05	0.151	0.8	1.10	0.130	0.4
C: Democracy/Download	1.04	0.151	0.8	0.99	0.129	>0.9
D: Democracy/Server	0.93	0.148	0.6	1.11	0.132	0.4
Age	0.97	0.023	0.2	0.99	0.019	0.7
Gender						
Woman	—	—		—	—	
Man	0.74*	0.145	0.038	0.88	0.134	0.4
Transgender/Nonbinary/Multiple/Other	1.19	0.194	0.4	1.33*	0.141	0.044
Prefer not to say	3.88*	0.612	0.027	1.59	0.303	0.13
Lived Experience						
FALSE	—	—		—	—	
TRUE	1.39*	0.151	0.028	0.94	0.143	0.6

[1] *p<0.05; **p<0.01; ***p<0.001
[2] OR = Odds Ratio, SE = Standard Error, IRR = Incidence Rate Ratio

To model the number of surveys completed we used a Hurdle model[18] with hurdle for completing more than the baseline surveys and counts data fit with a truncated negative binomial distribution (Table 6.e.4).

The results are highly consistent with the App Retention survival results (Table 6.e.3). In particular, participants in South Africa, and the UK are more likely to participate beyond the baseline (p-values < 0.001 for both South Africa and the UK) and complete more surveys than those in India (p-values = 0.01 and < 0.001 for South Africa and UK, respectively). Engagement Arm 2 shows more survey participation than Arm 1 (p-value = 0.003). As with the App Retention survival, there is no significant difference by Consent Model.

Active Ingredients

Participants in Arm 1 had a strong preference for the Sleep and Social Activity active ingredients relative to Positive Experiences and Body Movement. Body Movement was the least popular among participants in all countries, whereas Social Activity was the most popular across all countries (Table 6.e.5).

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Table 6.e.5: Active Ingredient selection (Arm 1) or Assignment (Arm 2).

Characteristic	N	Arm 1, N = 793			N	Arm 2, N = 847		
		India, N = 140[1]	South Africa, N = 136[1]	UK, N = 517[1]		India, N = 182[1]	South Africa, N = 161[1]	UK, N = 496[1]
First AI	793				839			
BodyMovement		8 (5.7%)	11 (8.1%)	40 (7.7%)		52 (29%)	32 (20%)	127 (26%)
PositiveExperiences		22 (16%)	17 (12%)	50 (9.7%)		46 (25%)	34 (21%)	113 (23%)
Sleep		49 (35%)	34 (25%)	194 (38%)		42 (23%)	47 (29%)	122 (25%)
Social		61 (44%)	74 (54%)	233 (45%)		42 (23%)	48 (30%)	134 (27%)
[1] n (%)								

Table 6.e.6: Model estimates for the effect of AI on the number of surveys completed, using a truncated negative binomial model with hurdle for completing more than the baseline surveys.

Characteristic	Zero Hurdle (Logisitic)			Counts Model (Neg Binomial)		
	OR[1,2]	SE[2]	p-value	IRR[1,2]	SE[2]	p-value
Country						
India	—	—		—	—	
South Africa	2.14**	0.268	0.004	1.45*	0.153	0.015
UK	3.62***	0.235	<0.001	1.54***	0.126	<0.001
Engagement Arm						
1	—	—		—	—	
2	0.84	0.203	0.4	1.36**	0.096	0.001
AI						
BodyMovement	—	—		—	—	
PositiveExperiences	1.15	0.285	0.6	0.75	0.156	0.060
Sleep	1.38	0.274	0.2	1.00	0.143	>0.9
Social	1.84*	0.279	0.029	1.00	0.142	>0.9
Age	0.97	0.043	0.6	0.99	0.019	0.7
Gender						
Woman	—	—		—	—	
Man	0.99	0.281	>0.9	0.91	0.134	0.5
Transgender/Nonbinary/Multiple/Other	0.95	0.350	0.9	1.32*	0.140	0.049
Prefer not to say	1.32	0.748	0.7	1.57	0.302	0.14
Lived Experience						
FALSE	—	—		—	—	
TRUE	1.61	0.266	0.072	0.92	0.142	0.6
[1] *p<0.05; **p<0.01; ***p<0.001						
[2] OR = Odds Ratio, SE = Standard Error, IRR = Incidence Rate Ratio						

This observed AI preference did not translate into statistically significant differences in 4- or 12-week study retention (4-week survival p-value = 0.29, 12-week survival p-value = 0.19) or survey engagement. The Hurdle model for survey engagement (Table 6.e.6) showed that relative to participants with assigned to or selecting the Body Movement AI all other AIs were more likely to participate beyond the baseline, but this effect was only statistically significant for the Social AI (odds ratio (OR) = 1.84, p-value = 0.029). However, once participating in the AI, Body Movement, Sleep and Social showed very similar survey participation. While not statistically significant, the survey participation for Positive Experiences was slightly lower (incidence rate ratio (IRR) = 0.75 relative to Body Movement, p-value = 0.06).

Passive Data Collection

The proportion of participants providing background recorder/passive data was reflective of the country-specific trends for App Engagement, with increasing proportions participating in South Africa, India and the UK (Table 6.e.7). It is important to note that across all countries, the Ambient Light passive recorder was present in fewer participants than the other passive recorders. This may be reflective of data loss, especially given that the drop is most acute in South Africa and the UK (See the "Technical Considerations" section for more details). These files tended to be the largest of the passive file types (typically around 50 MB in contrast to the others which tended to be < 10 MB).

Table 6.e.7: Participants providing passive data as a proportion of those who completed the "About You" baseline survey (for consenting to the study).

	India	South Africa	UK
Ambient Light	21.6 (10.0)	14.6 (6.0)	24.1 (17.7)
Battery Statistics	28.6 (13.2)	26.1 (10.8)	39.3 (29.0)
Charging Time	25.8 (11.9)	23.0 (9.5)	36.8 (27.1)
Data Usage	28.2 (13.0)	23.5 (9.8)	34.9 (25.7)
Screen Time	29.6 (13.6)	24.6 (10.2)	42 (31.0)

The duration of contribution and number of records shared also reflected the same patterns as active data contribution (Table 6.e.8) with participants in India contributing for shorter duration and smaller number of records, followed by South Africa and with UK participants contributing the most.

Table 6.e.8: Number of records and duration of passive data contribution

	India				South Africa				UK			
	# of Records		Duration (Days)		# of Records		Duration (Days)		# of Records		Duration (Days)	
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median
Ambient Light	15.3 (17.1)	9	21.9 (22.1)	15	15.9 (14.5)	12	23.5 (21.1)	15.7	26.5 (21.4)	18	33.0 (26.3)	24.5
Battery Statistics	16.3 (17.0)	10	23.4 (22.2)	16.1	18.2 (15.4)	15	26.5 (22.3)	18.9	26.7 (21.0)	19	33.1 (25.5)	26.1
Charging Time	16.6 (17.8)	11	22.1 (22.6)	14.9	18.5 (16.2)	14	27.5 (22.0)	24	27.4 (21.1)	21	34.0 (25.8)	27
Data Usage	16.3 (17.1)	10	23.1 (21.9)	16.1	16.3 (14.6)	12	24.7 (21.8)	18	26.9 (21).0	19	33.1 (25.7)	25.8
Screen Time	15.5 (17.0)	9	21.7 (22.1)	14.3	18.4 (15.6)	14	26.9 (21.9)	23.1	26.7 (20.9)	19	32.7 (25.4)	25.6

Final Week Feedback

In the final week of the protocol, AI-specific short surveys were replaced by questions about the study experience. Results in Table 6.b.1 detail the responses to the closed-ended questions. Participants typically reported that the insights provided to them about their past responses as well as the GIFs at the end of the long surveys were generally engaging. This implies that future work to make the app more insightful and visually appealing may be useful.

Participants also submitted open comment responses to the questions "Finally, if there was a way for us to make the experience more engaging, what do you recommend?" and "So, did you come up with any ideas for improving the experience you just went through? Please tell us about them." A content analysis of these responses is below.

App features

Many respondents expressed a desire for reminders or notifications to participate in the study:

> *"reminders in the form of notifications as I forgot to do some days"*

> *"the ability to set reminders from the app would be really useful"*

> *"Option for notification each day so people don't forget to complete survey"*

Participants made note of GIFs, memes, emojis, and other visual rewards and desired more of these:

> *"Cute memes and gifs at the end of the questions more often, seeing them made me smile on worse days and feel happier on good days."*

> *"I appreciated the little memes and GIFs at the end of the questionnaires sometimes."*

> *"the multiple choices are really good and if you could add some smilies* [sic] *or emojis to be choosed* [sic] *given each one indicating a mood or so.. it would be more engaging"*

Participants expressed a desire for more variety in questions:

> *"Wider variety of questions, could be repetitive at times"*

> *"change the questions a bit so it doesn't feel repetitive and like a chore to complete."*

> *"have a variety of questions rather than the same for a long time"*

Or "fun facts" to keep things interesting:

> *"Maybe add some fun facts about any recent research in this or other university so that we have something else to look forward to."*

> *"Just maybe putting in fun facts on research or insights on uncommon topics to make it more interesting."*

Participants as co-researchers

Respondents also evinced a desire to influence the study design as co-researchers. We have seen this previously in the open comment responses in the mPower study[19], and this is an area of inquiry in Bridging the Gap (a sub-study of MindKind funded by Wellcome).

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Participants recommended that their information be aggregated in an informative way as a means of returning value:

> "It would be nice to be able to go back and see summaries of previous weeks to see how my mental health was in the past compared to now and see if anything had changed. Maybe also being able to track other health related measures such as weight or menstruation as well."

> "more information about previous responses to the questions or visualizations of trends (eg a graph of mood over time)"

> "a graph showing the data would have been good, so I could see what times I was falling asleep etc."

> "Being able to good back to previous weeks and see how I was doing would be great and would also make the first of page you see when you click on the app look less boring because there is usually only one thing there."

> "And it would have been nice to be able to look back at my previous responses, or have a recap/report of the end of each section, eg with graphs showing my mood, exercise/social interaction/positive experiences etc during that phase of the study"

They shared their observations of types of knowledge that are not captured by the study:

> "During the study, I noticed some answers couldn't reflect what's happening or what's causing the results. For example, I would be in a bad mood after having a long night and the mood not be related to the amount of sleep I got. I suggest next time we get allowed to write something like a journal of all that happened during the day and say what made us feel the way we do"

> "often when i said I didn't do anything social in a day the questions ended for the day. maybe in could have been better if it asked for my opinion if my meed [sic] felt worse for not being social"

> "Asking questions about if an event had happened to affect my mood. Such as getting bad or good news, as this is a key factor in how I feel each day, not just sleep or exercise"

As well as ways in which the data collection tools could be better designed:

> "I often go to bed after midnight which meant I was answering for the wrong day."

> "it's hard to accurately count how many minutes of physical exercise I have done in a day especially when my job entails me to be on my feet and moving around for the whole day. maybe hours instead of minutes to count it"

> "If you misclick it would be nice to go back and change your answer."

> "maybe more options for mood, for example you might be feeling more than just "bad mood" but not quite "worst ever" so which one do you pick??"

Therapeutic misconception & the capacity of digital tools

Finally, some responses indicated a possible therapeutic misconception (see Section 8.g "Misunderstandings") about the function of the app and its (in)capacity to improve mental health:

> *"I did not improve my experience, I just happened to get a job and things just got better and the pressure I had was gone. It doesn't mean I'm completely better and healed. I'm still going through stuff but I'm handling it better. I'm healing and I'm doing shadow work and I'm trying to be as self aware as possible."*

> *"I have decided to work more on myself and create my dreams"*

> *"I realised the importance of sleep, food and doing something for myself everyday"*

> *"I have, Not always thinking about the problem, finding someone whom you can talk to and just doing something you really loves improves one's mood"*

> *"to feel better, I try to acknowledge my feelings as normal and not feel guilty about how others will perceive because I will explain it to them later after I am ok with my own feelings first*[.] *also calm myself using breathing techniques and meditation"*

While these types of responses may evince a therapeutic misconception among participants[19], equally they may be artefacts of the evolving research landscape[20]. Research apps, in their mere contextual placement on devices integral to people's connected lives, can blur the line between research as a search for generalizable knowledge and individually-focused care[19,21]. The line between research and clinical care is further muddied by the vitally important movement for inclusion of people with lived experience in health solving. We will never capture the deep and granular data nor the diverse insights needed to address complex health questions like mental health without engaging participants as co-researchers. Prompts that we gave participants, such as those asking participants to share insights into their mood or to consider the relationship between their previous week's mood and AI responses, are in line with this framing of participants as solvers. It is unsurprising, then, that respondents to the final week survey spoke to the behavioural changes they attributed to the influence of the app. That participants found utility in the app is an added—although not intentional—benefit. However, these responses do give pause: future designers should not only be thoughtful in how they engage participants about their lived experience, but also explicit in the limits of the intention and capabilities of the data collection app.

Recommendations

- Participants offered a choice of AI topics showed reduced participation relative to participants who were assigned AI topics. Therefore, we recommend not including AI choice in future studies.
- For passive data collection, limiting the size of files generated is recommended in order to minimise potential data loss.
- This pilot implemented a minimal design phase and set of approaches to boost engagement. Participants, as well as study team and advisory board members, identified a much more extensive set of engagement features (above and Section I.7 (below)). Recommendations are listed in Section V.

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7. Technical considerations

Abstract

In order to implement the MindKind quantitative study, the research team developed a custom website for study enrollment and a bespoke Android application which presented the study surveys and collected passive data for participants who opted in. Both the website and study app interfaced with the Sage Bionetworks Bridge server for secure, encrypted data transfer and storage. The Bridge server exports de-identified data to the Synapse data sharing platform for access by researchers. We also developed minimalistic recruitment dashboards for tracking by the study teams. In all cases, we have documented requirements for an ideal study even when meeting those requirements were not feasible for this pilot study due to time and budget constraints.

a. Participant-facing technology

Approach

The MindKind research study technical implementation approach was designed to address a minimum set of requirements for information distribution, technical implementation, and data governance. To fulfil these requirements within the allotted time frame, our approach was to construct a website for the information distribution and multi-language informed consent and enrollment requirements, and a mobile application to collect survey study data.

Table 7.a.1: Minimum requirements for information distribution, technical implementation, and data governance

Information distribution	Technical implementation	Data governance
Provide informed consent with sufficient multi-language support per global location	Use participant sign-in on both the web and smartphone applications to verify that the same user completing enrolment is the same user submitting survey data	Collect data from three distinct global locations in compliance with GDPR and country specific policies
Provide direct access to country specific mental health resources	Actively restrict enrollment of participants based on exclusion criteria and location without IP address tracking	Collect minimally invasive phone background data
Provide sufficient information about the research team, funder, and study background	Conduct locale specific survey data collection and adhere to logic structure of study protocol	Protect participants' rights through persistent and direct access to privacy policies, opt-in and opt-out controls, and transparent de-identified data collection
Potential to serve as a future public-facing informational resource to inform prospective participants about future research studies and publications	Minimise data bandwidth consumption to be cost-conscious for global consumers	Adhere to all privacy and security requirements for data-at-rest and data-in-motion
Clear and accessible descriptions of participant rights	Maximise access to the study by enabling as many globally supported devices as possible	Empower users to withdraw from the study, request data deletion, and copies of their data
	Deliver the technology in a way that is engaging and accessible to the demographic	
	Provide aggregate clickstream statistics without using cookies or other PII	
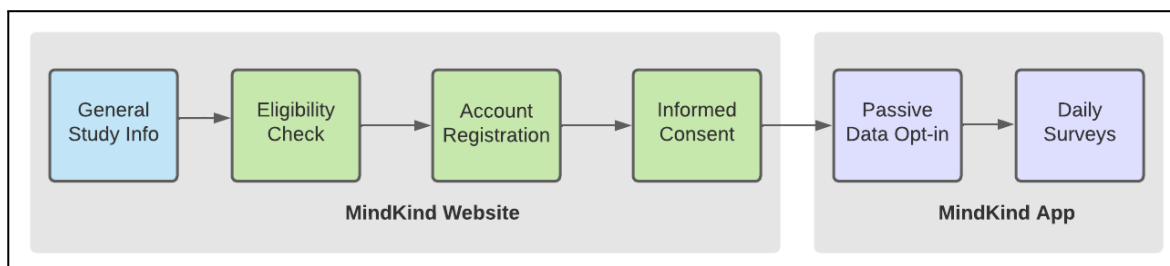
Figure 7.a.1: Study technology consisted of a website for dissemination of general information and informed consent. Participants were then directed to download the study app for active and passive data collection.

Website implementation

The enrollment website was designed 'mobile first' to address the fact that most of the target demographic accesses website information through a mobile form factor. The website was deployed globally using AWS CloudFront content delivery network (CDN) service. Website source code is publicly available under the BSD-3-Clause licence through the GitHub repository https://github.com/Sage-Bionetworks/GlobalMentalHealthDatabank.

The website was implemented as a public website accessible by anyone with internet access. Since the privacy requirements prevented the collection of IP addresses, it was not possible to restrict the website to only the three specified global locations. We therefore took basic, pragmatic technical measures to target content to the desired countries. However, the mobile application was restricted to publication and download only within India, South Africa and the UK. Since IP addresses could not be used to verify the country of the potential participant, country/region code matching during enrollment on the website and the country limit on app store publication helped to validate that participants were actively in-country for participation in the study. This was important to ensure that participants were subject to the appropriate in-country data and privacy policies. Participants with out of country phone numbers for example, even if residents of a valid country, were therefore excluded from enrolling in the study since their location could not be confirmed.

Once exclusion criteria and country code validation were successfully completed, the participant was guided through an enrollment process of informed consent. The participants were informed of the purpose, benefits, and risks of participating in the study and were provided access to an informed consent document in their language of choice (English, Xhosa, seSotho). At the end of the enrollment process, participants electronically signed and acknowledged their consent to participate. After consent, the website redirected participants to download the Android mobile application to proceed with the quantitative study activities.

Limited, de-identified, cookie-less clickstream data was collected and aggregated using Google Analytics. This data was used to help assess participants' dropoff points as they progressed through the enrollment process, and to assess the referral traffic from various sources of referrals like social media sites and direct URLs. Google Analytics anonymous Client Identifiers (CIDs) were used to count individual users of the website, but with cookies disabled no identifiers were ever written back to the user's device, to comply with GDPR policies. This method introduces some inflation error into the clickstream data. For example, users who were not signed in and manually reloaded browser pages or closed their browser

window and later returned to the website would generate a new CID and were counted as an additional distinct user session. This inflation error **only** applies to browser session counts prior to phone number registration and **does not apply** to explicit responses to questions provided by each individual participant as they progressed through the enrollment and consent process (e.g. as accounted in Section 6.d).

Mobile Application implementation

Timeline and resources allowed for only one mobile development platform. Since the Android platform supports the widest variety of global device availability[22] and price points, we selected the Android mobile development platform and deferred the iOS platform. The mobile application was developed to support devices running Android 6 or greater. Mobile application source code is publicly available under the BSD-3-Clause licence through the GitHub repository https://github.com/Sage-Bionetworks/MindKind-Android. In addition to meeting technical, privacy, and security requirements, the mobile application was intended to present and use different engagement strategies. Engagement strategies were envisioned to keep participants actively participating and engaging daily with the app throughout the 12-week study. Each strategy was evaluated and scoped according to the feasibility of the development timeline.

Table 7.a.2: Proposed and implemented engagement strategies

Proposed engagement strategy	Actual implementation
Comfortable, familiar interface to make the app feel more personal and engaging	Surveys and responses presented as a familiar chat/text thread common to most IM and SMS interfaces (Figure 7.a.2).
Return of information to participants including aggregate statistics of other participants, relative progress, and interpretations of responses relative to other participants	Deferred. Instead, summary counts of an individual participant's response values through the study were presented weekly to each participant, along with an overall study progress bar.
Access to an in-app community support forum	Deferred.
"Rewards" for activity completion including .gifs or short videos	Participants were presented with .gifs after completion of long surveys.
Journaling	Once weekly, participants were prompted to journal about a topic related to their AI or general mental health. These entries were not accessible by participants for viewing or editing once submitted.
Inspirational messages	Survey salutations and completions were randomised to present a variety of encouraging statements.
Visualisation of geo-location and counts of other participants in the study	Deferred.
Messages from the research team presented as intermittent short videos throughout the study to personalise the study	Deferred.
Gamification	Deferred.
Study pause or "vacation mode" for participants to pause the app when they know they will not be able to participate for several days (e.g. during exams) and then return to where they left off in the study.	Deferred.

Feasibility evaluation was done on existing implementations of phone background data collection Android Software Development Kits (SDKs) to try to gain efficiencies in the development pipeline. SDKs were evaluated that are relevant for cognitive/mental health data collection. PassiveDataKit audacious-software/PassiveDataKit-Android was evaluated and rejected. PassiveDataKit has not been updated since 2016 and would require significant effort to implement and maintain it. The Aware framework https://awareframework.com/ was evaluated and rejected since its permissions model does not follow current Android development guidelines for privacy. Additionally, Apps using the Aware framework cannot

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be published in the Google Play Store. As a result, the mobile development plan was to directly implement each background recorder to ensure quality, accuracy, optimization, and ethical governance of each data stream.

The selection of background data recorders considered several factors. First, the invasiveness of each recorder was evaluated. A recorder was rejected if it required an active scan of a participant's phone as opposed to recorders that could be accessed via a passive listener or a summarised metadata-API. For example, collection of WiFi network data or connection information about Bluetooth devices that are nearby the participant were rejected because the Android platform does not currently provide a summarised record of WiFi information.. Due to abuse from predatory apps, the Android platform continues to evolve and throttles many types of background collection, especially in newer versions. Therefore, implementations of background recorders need to be continually evaluated and future collections may not be at parity with current collections.

Figure 7.a.2: Chat UI design

Next, each background recorder was evaluated for flexibility to optimise for minimal data upload size, minimal impact to the participants' phone, and the presence of tunable parameters such as frequency and duration windows of collection time (Table 7.a.3). Impact on user's battery consumption, data upload/bandwidth costs, and phone performance were considered. Additionally, background sensors vary greatly amongst device types, with newer devices having a greater range and fine-tuning of features.

Table 7.a.3: Proposed and actual implementation of background recorders for Android mobile development platform

Proposed background recorder	Description	Restrictions	Actual implementation
Ambient light	Detect ambient light in the device environment	Passive listener. Do not use camera to collect light data since camera access scope is too broad (i.e. potentially invasive). Instead, use light sensor only despite lack of universal availability. Presence is detected by the OS.	Sampled for 10 seconds every 15 minutes at 5Hz
Screen time	Summarise device screen off and on states, and when the user is present and authenticated within the app	Passive listener	Count of screen off and on states
Battery statistics	Summarise device battery drain	Passive listener	Sampled every 60 minutes
Charging time	Summarise time spent charging the device	Passive listener	When phone is plugged in and unplugged
Data usage	Detect how much data is consumed by the device	Passive listener	Total bytes that have been uploaded and downloaded over wifi and cellular combined
Daily weather	Collect local weather data	Requires opt-in for use of participant location, either zip code or approximate GPS location (not precise location)	Deferred
Air quality	Collect local air quality data	Requires opt-in for use of participant location, either zip code or GPS (not precise GPS)	Deferred
Step count	Collect step count using the device as a pedometer	Step counter and step detector sensors require Activity recognition permission and/or Health Connect integration. Potential for battery drain requires significant testing to optimise for interval sampling. Raw accelerometer and gyroscope require post-processing	Deferred
Activity recognition	Detect when participant is moving vs. stationary and whether they are walking, sitting, running	Requires opt-in for use of participant location, either zip code or GPS (not precise GPS) and/or Health Connect integration	Deferred
Device interaction time	Summarise how much total time is spent using the device	Not available as a summarised API. Requires app-level OAuth	Not recommended
Wifi	Collect number of wifi networks available in the vicinity of the device	Not available on Android as a summarised API. Requires invasive phone scan	Not recommended
Bluetooth	Collect number of Bluetooth devices available in the vicinity of the device	Not available on Android as a summarised API. Requires invasive phone scan	Not recommended
Social media use (Instagram and Facebook)	Collect login times, timestamps of posts and views but not content of posts and views	Not available as a summarised API. Requires app-level OAuth	Not recommended

Analogous evaluation of existing SDKs, invasiveness, and optimization was not performed for the iOS platform and would need to be performed prior to building an iOS application to achieve reasonable parity with the Android application. In general, iOS provides more limited access to passive user data than Android.

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Learnings

Global considerations

A fully remote, global study has unique technical challenges. A primary challenge is ensuring that each participant can be assigned a unique identifier. In traditional studies, a study coordinator typically assigns a unique randomised identifier or a GUID. Since a remote study has no contact with a participant prior to their instantiation within the system, a mobile phone number was used to uniquely identify each participant and enable a verification step via a SMS link. However, SMS delivery varies greatly from country to country and from carrier to carrier. Many countries treat their mobile trunk lines differently than standard lines, leading to variation in allowable exchanges. Carriers may choose to block SMS messages on behalf of users to prevent 'spam' messages or to maintain data and cellular plans with a cap on allowable number of messages per month. Participants may directly opt-out of receiving SMS messages, preventing a resend of a verification code. All of these scenarios can lead to loss at the entry point of participation within the app.

Amazon Simple Notification Service (SNS) was used to send SMS messages to participants for sign-in verification. Specifically within India, there are special requirements for use of SNS[23]. This process involves registering with the Telecom Regulatory Authority of India (TRAI) in partnership with India Vodafone/Vilpower. Additional server development would be required to be compatible with the process. Without this registration, we estimated a 30-40% drop in participants who wanted to enrol but could not receive a verification SMS. To resolve this issue, we learned that we could still use a participant's phone number as a unique identifier, but we needed to add a user generated security PIN code for a verification process. Users in India would generate their PIN during enrollment on the website, and later use it to sign-in to the mobile application.

App Engagement

As discussed in section 6.e, the notable drop-off between consent and app engagement, particularly in India and South Africa, may represent technological barriers to participation in these countries which may be tempered by the development of additional platforms. Including a web-based platform, while lacking in features like collection of passive data, may improve accessibility and representation.

Data Integrity

Data loss is a primary concern in any remote study. It is especially hard to predict and prevent in an untested global context across a wide variety of devices, connectivity speeds, and bandwidths. Data loss was anticipated to occur at the critical point of the data upload from the device to the server. This upload requires active internet connectivity and can be easily disrupted if a connection is dropped during upload or if the app is placed into the background and not relaunched. In regions or carrier plans with lower connection speeds and lower bandwidth, this may be more likely to happen especially with larger files.

To try to quantify data loss, we compared participants' stored AI with the AI inferred from study completion + stored AI. In India, South Africa and the UK, respectively, we observe 1.6%, 14% and 8% missingness of AI annotation. While this is almost certainly an underestimate of data loss, it does give us some insight into data expected vs data

observed. It is important to note that due to the much lower engagement in India, the bias (underestimation) is likely greater in that jurisdiction. For larger files, data loss may be larger. For example, the relative ratio of Ambient Light passive files (> 50 MB) to Battery Statistics passive files (typically < 1 MB) 0.69, 0.47 and 0.61 for India, South Africa and the UK, respectively.

Software bugs are a normal part of the development process. The goal is to minimise the introduction of bugs into the production application and respond quickly to issue reports if they do arise. Bugs are triaged according to the impact they have on critical functionality to the participant. Some issues are only discovered retrospectively when they are identified through anomalies found during data analysis. Due to the very rapid timeline of this project, there was limited ability to test and debut the app across the wide variety of geographic areas, devices, and internet access characteristics we experienced. A longer-running study would have more time to react and mitigate technical issues with data collection. Testing in each locale is critical to identifying bugs unique to a specific infrastructure.

Issues such as the SMS sign-in issues within India, incorrect screen layouts on certain phone models, and updates to alerts were identified in real-time. Fixes were deployed into production, resolving issues for current and future participants. Other issues were identified retrospectively through data analysis. Notable issues are data loss in annotation of AIs, the lack of assignment of AIs to some users resulting in the participant not receiving subsequent daily survey questions, failed uploads of larger background recorder files, and an inconsistent mapping of the End of Study day, leading to extended data collection from some participants beyond the 12-week study period.

App Usability

Participants withdrawing from the study were prompted to participate in an exit survey. While survey participation was low, most who completed the survey indicated that they found the app easy to use and quick to learn.

Table 7.a.3: Exit survey usability results.

Statement	Strongly Disagree ←-------------→ Strongly Agree					Mean
	0	1	2	3	4	
I found the study app unnecessarily complex.	3	3	1			0.71
I felt very confident using the study app.					5	4
I found the study app very cumbersome to use.		2	2			1.5
I thought the study app was easy to use.	1			3	3	3
I needed to learn a lot of things before I could get going with the study app.	2	3				0.6
I thought there was too much inconsistency in the study app.	2	2			1	1.2
I found the various functions in the study app were well integrated.		2	3	1		1.83
I would imagine that most people would learn to use the study app very quickly.	1			2	2	2.8
I think that I would need the support of a technical person to be able to use the study app.	1	3		2		1.5
I think that I would like to use the study app frequently.	1	2		2	1	2

Recommendations

Constructing a solid app experience for global distribution with minimal bugs takes time, effort, and infrastructure. To progress beyond a pilot/feasibility study, the recommendation is to allow at least a one year timeframe for feature development in parallel with development of infrastructural support and finalisation of a study protocol. We recommend support for feature and infrastructure development for test automation and coverage, communications, and post-release monitoring in each jurisdiction. In addition to more robust technical measures, sufficient participant technical support to help understand and resolve participant issues would be needed for a longer-running study.

Feature and infrastructure development

- Alleviate common data upload issues by improving queueing, caching, partial data save, and retry capabilities
- Improve data analysis efficiency with improved data annotation
- Refine parameters for background recorder data collection to reduce data file size
- Re-evaluate the impact on the study protocol of repeating survey questions that were not captured due to technical failure
- Revisit additional engagement strategies features
- Implement test automation support
- Reduce complexity of having both a website and mobile application by adding in-app multi-language support and localization tooling
- Simulate testing over a large number of device types and/or employ a device farm for testing
- Tooling for A/B testing to inform early app design to improve engagement features

Communications

- Consider protocol approval to add an active messaging mechanism such as FCM (Firebase Cloud Messaging) to dynamically communicate with participants for automated reminders or other procedural push notifications
- Implement a customer support helpdesk to capture feedback and issues from users to track progress to resolution and closure

Post-release

- Implement Tests in Production (TiPs) to continuously monitor and trigger alerts when functional breaks occur. For example, TiPs would have caught the issue that some participants encountered of not receiving an AI assignment and/or not receiving daily survey questions
- Implement crash reporting and error log collection mechanisms such as Firebase Crashlytics to provide key reproducibility information necessary for developers to fix issues

b. Technical considerations - database privacy and security

Approach

Strict information technology procedures to safeguard information and prevent improper access are employed on all Sage Bionetworks products and services, including the Synapse Research Platform (www.synapse.org), Bridge Server (study management server), Mobile Applications, and Web properties. Amazon Web Services (AWS) provides the base layer for all services. AWS is the world-wide leader in cloud computing and provides security

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measures at the physical and network layers that comply with strict federal requirements including the standards of HIPAA (http://aws.amazon.com/compliance/). Account information is encrypted at rest, as documented in Encrypting Amazon RDS Resources (https://docs.aws.amazon.com/AmazonRDS/latest/UserGuide/Overview.Encryption.html).

Bridge and Synapse web services are maintained by discrete teams of systems administrators, directly employed by Sage Bionetworks. The number of IT employees with access to the data for the purposes of administration is limited. All system access is recorded in logs for security and auditing purposes. Data are encrypted for storage and transfer, and so cannot be accessed by any subcontract infrastructure provider (i.e., AWS). Additionally, all databases require Secure Socket Layer (SSL) connections.

Bridge Server for Data Management

Sage Bionetworks' Bridge Server is a study management service to enable diverse mobile health studies, and supports studies both internal and external (unaffiliated) to Sage Bionetworks and its researchers. Bridge Server is designed to securely manage research data collected through mobile technology platforms. To date, it has supported management of longitudinal data collected directly from over 230,000 individuals in digital health studies including data collected through questionnaires, passive monitoring, structured and unstructured written responses, images, and linkage to external databanks including for wearable integration.
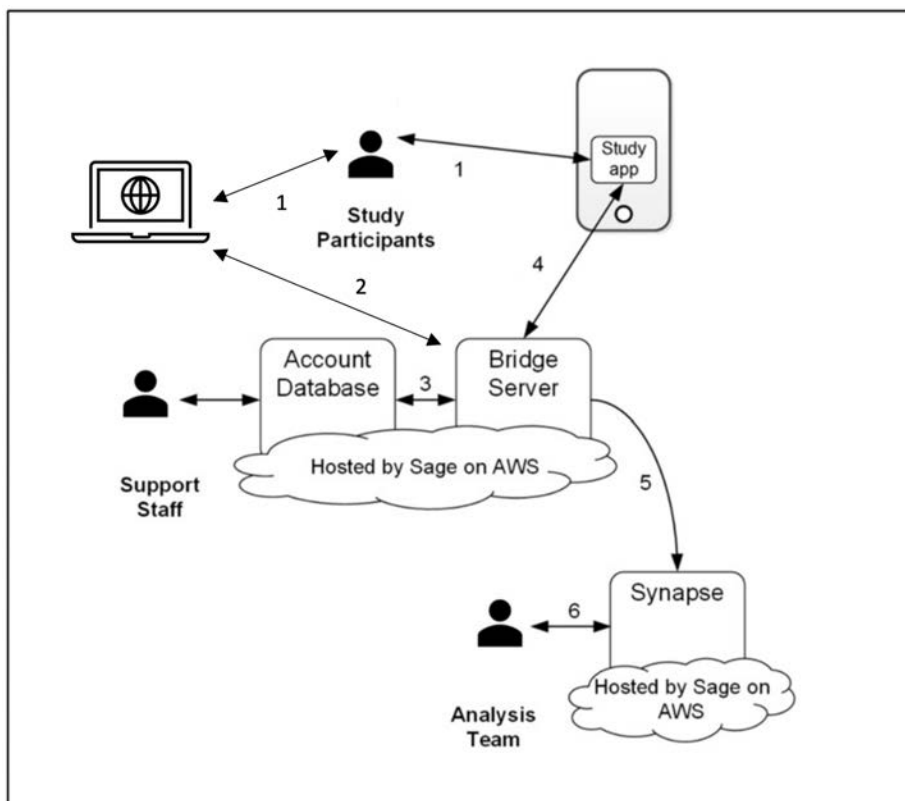
In Bridge, study participant account and contact information (i.e., personally identifiable data) is kept separate from the participant study data and is only accessible to key IT staff and study organisers. For the purposes of the MindKind pilot study, this meant a small number of the Sage Bionetworks team and did not include site personnel.

Figure 7.b.1: Bridge server architecture.

The account management service automatically generates a unique random identifier called a healthcode that is associated with participant study data and maintains an encrypted mapping between participant account and participant study data. This way, in the rare event that either the databases hosting the account information or the study data is compromised, the connection between personal identifiers (name, phone number) and her/his/their health/study data will remain protected as shown in Figure 7.b.1.

1. Participants interact with the enrollment website via computer or smartphone (prior to consent), or the study app (following consent).
2. During study registration and consent, the website creates a verified account for the participant with Bridge. As part of enrollment, study participants may provide personally identifying information (PII) to create an account (e.g., email / phone number).
3. Bridge stores participant PII in the account database, and generates a unique, random identifier for each participant called a healthcode. The account management service automatically generates this unique random identifier that will be associated with participant study data and maintains an encrypted mapping between participant account and participant study data. Thus, researchers analysing the coded study data will not know the identity of the participants.
4. As the participant completes activities in the app, data is uploaded to Bridge Server, mapped to the participant's unique identifier, and cached by Bridge Server.
5. Coded study data is periodically exported to Synapse, typically on a nightly basis.
6. Data is made available to the study analysis team via secure APIs. Synapse provides support for data analysts to work with study data, while separating them from access to personally identifiable account data.

Other steps to preserve participant privacy include:
- The participant's identity or IP address is NOT sent from the smartphone or the website to Synapse.
- Phone numbers are NOT collected from participants who do not meet eligibility criteria and Bridge Accounts are NOT created.
- Prior to account registration, web session meta-data and anonymous identifiers were used on the website to retain the participant's position in the consent flow if they closed their browser or wished to complete their consent at a later time.

This approach protects the privacy and data confidentiality of the study participant and promotes the appropriate use of the data in future research by limiting subject re-identifiability.

Synapse for Data Access

Synapse can be used to manage data sharing internally and for data dissemination. The study data collected from both the website and the mobile application are stored on Synapse using a combination of Amazon S3 and MySQL.

Synapse operates under a strict governance process that includes Terms and Conditions of Use, guidelines and operating procedures for handling data, data security measures with strict information and privacy-enhancing technologies, as well as the right of audit and external reviews (WIRB 20112068). The Privacy-Enhancing Technologies options include

login requirement, data, and communication encryption via Secure Sockets Layers (SSL) when transmitting data or command, firewalls for both ingress and egress, and authentication and authorization of users who access the limited data on Synapse (http://docs.synapse.org/articles/governance.html).

Synapse can be used to manage data sharing within the project team through a team and role permissions design. For within-project data sharing, Synapse users can request to join or be invited to a team. Adding a Synapse user account to a team requires approval by a team manager. This management permission system was used for data access by the distributed members of the MindKind study team.

For the purposes of sharing data outside the study team (i.e., for databank dissemination), data can be shared under specified governance models using additional tools and procedures to verify researchers' identities (Qualified Researcher Program) and manage data governance requirements. These researchers are never granted access to data in Bridge, only the curated and vetted data in Synapse.

The coded study data will be made available to Synapse Qualified researchers to use in future research. Synapse Qualified Researchers are individuals who (1) have passed the Synapse certification quiz and have a validated user profile on Synapse, (2) agree to the dataset-specific Data Use Conditions including appropriate acknowledgment and citation, and (3) provide a brief Intended Data Use statement to be posted on Synapse with their name and affiliation.

Qualified researchers analysing the coded study data made available through Synapse will not know the identity of the study participants. They cannot remap the data to the participant identity or access identifiable data in Bridge.

Synapse is actively used in the support of a variety of NIH funded research communities and data sharing initiatives including half a dozen Alzheimer's programs (https://adknowledgeportal.synapse.org/) and related results explorers derived from those data (e.g. https://agora.adknowledgeportal.org/ and https://sagebio.shinyapps.io/MODEL_AD_Explorer/), as well as the PsychENCODE (https://psychencode.synapse.org/), and Cancer Systems Biology Consortium and Physical Sciences in Oncology initiatives (https://cancercomplexity.synapse.org/) to name a few. Additionally, Synapse is actively used to store, manage and distribute data from over 30 digital health research studies (https://dhealth.synapse.org) and including over 160,000 research participants.

Learnings

In order to scale a potential Global Mental Health Databank, future development of an automated procedure to manage requests for data deletion and providing copies of data to participants, and proof of completion of the requests, per GDPR requirements. In the current implementation, this is a manual process carried out in response to an explicit request in writing from a participant.

Data export and storage of data outside borders is increasingly becoming a point of contention by ethical review boards. In India in particular, documents such as signed consent

forms that contain PII must be stored both electronically and physically within India country borders and cannot be physically or electronically retained on servers within US borders. To resolve this issue, signed consent forms were automatically forwarded to the India site team. The India site team then implemented their own electronic and physical retention policy. Signed consents in the form of .pdf documents are routinely deleted from Sage Bionetworks cloud servers after a period of 30 days. The record of consent is retained on Sage servers indefinitely for audit purposes.

To avoid such ad-hoc processes, a future databank may require standing up within-border server instances. The split of Sage's data platform between Bridge and Synapse is designed precisely to solve the problem of supporting future geographic diversity, by separating the services needed to support study managers interfacing with participants and their PII in Bridge, and providing access to de-identified data for analysts in Synapse. This approach would keep all PII associated with study participants within country boundaries. Furthermore this approach is not cost-prohibitive, as long as the target country contains an AWS data centre. Porting Bridge to run on infrastructure other than AWS is also technically feasible, although would come with higher costs and development timelines. Our *technical* recommendation is that de-identified data be consolidated in a single data centre to support analysis, as forcing analysts to work with data in several different jurisdictions would make the process cumbersome, and could impair the ability to perform some types of analysis and extract maximal knowledge from the data however this approach may not be compatible with various regulatory regimes. For our platform, storing data centrally would mean using Synapse, hosted in the US, for data distribution to researchers for analysis.

Recommendations

For larger international studies, consider infrastructure to stand up regional Bridge server instances for more flexibility in meeting country requirements for cloud data storage and processing outside of physical in-country servers. This would involve a gap analysis of all Bridge services in the intended country and an effort to remediate any missing services or services that do not have functional parity. Deployment and monitoring infrastructure would also need to be expanded to cover this distributed network of servers.

c. Study team-facing technology

Approach

In order to aid the study sites in understanding recruitment metrics, we developed a simple recruitment dashboard displaying the current recruitment stats showing all participants, as well as those with self reported Lived Experience. The dashboard also displayed a plot of enrollment by day. Sage is also actively developing a more powerful and capable study manager's dashboard as part of other work. While not available for this study, improved tools for tracking and communicating with study participants would be available in future studies utilising Sage's study infrastructure.

India Enrollment

Total Enrolled ↓⁼

986

Last updated on 6/24/2022 5:23 PM

Lived Experience ↓⁼

868

Last updated on 6/24/2022 5:23 PM

Enrollment by Day

■ activities
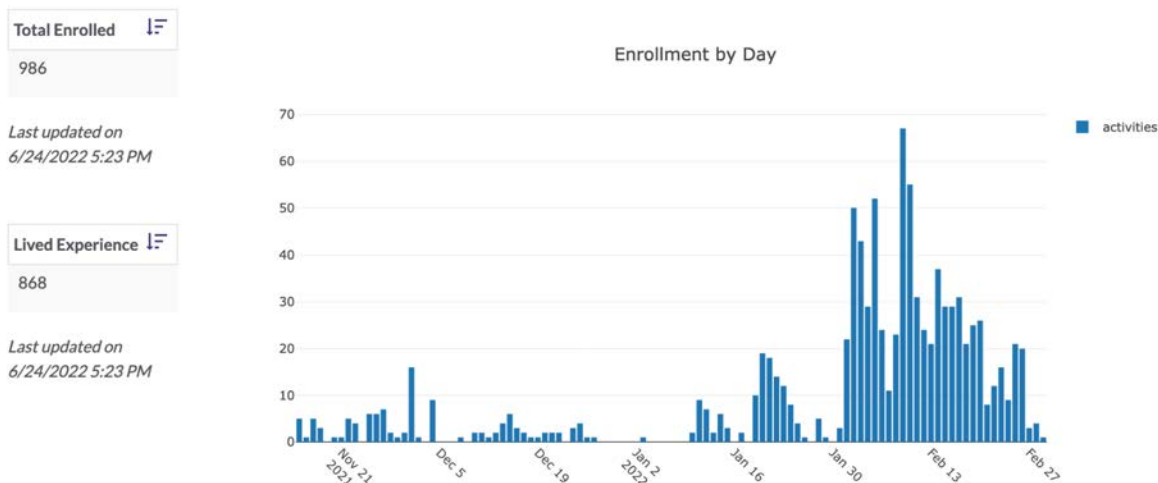
Figure 7.c.1: Researcher-facing recruitment dashboard

Learnings and Recommendations

Because most of the sites employed multiple recruitment strategies simultaneously, the study teams regularly requested more detailed information about the previous week's recruitment including gender and participants' answer to the question "How did you hear about this study?", which was asked after the eligibility check during enrollment. The sites used this information to help them adapt their recruitment strategies to widen their reach, invest in strategies that are more effective and/or target a specific demographic. Future recruitment dashboards should automatically integrate this type of information.

Because of the requirement to not track participants via cookies, the question "How did you hear about this study?" should also include text message and email options.

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8. Qualitative study design and analysis

Abstract

The qualitative study recruited n=158 participants ages 16-24 to participate in a two-round deliberative democracy process investigating the consensus data governance model(s) and concerns, hopes, and expectations of participants for a mental health databank. As is typical in deliberative democracy studies, this endeavour began with dissemination of materials to educate participants about data governance and their choices therein. Participants attended Round 1 (in-country) remote deliberative sessions wherein facilitators solicited their preferences on a seven question data governance typology. A selection of participants attended Round 2 (multinational) remote deliberative sessions to build consensus on this typology as a group. This process led to a set of more and less acceptable data governance options as well as major arguments and deeper thematic undercurrents of participants' reasoning, including the desire to *control the data* versus the feeling that one *can't control the data* and the *costs* versus *benefits of data sharing*.

a. Protocol design

The aims of the qualitative study arm are (1) to identify the consensus data governance model(s) for an open—yet privacy preserving—global mental health databank from the perspective of pan-national youth (India, South Africa, UK) and (2) to understand the concerns, hopes, and expectations of pan-national youth for such a databank with regards to (a) return of value to youth participants and (b) youth participation in databank governance.

A qualitative study workgroup (Appendix I.8.a.1) was convened to develop the qualitative study arm protocol and plan implementation, meeting seven times between November 2020 and February 2021. The Sage team provided a literature review[24–33] (details in Box 8.a.1) addressing youth perspectives on the collection and use of their private data to seed the conversation (Appendix I.8.a.2). Key takeaways included:

- Lay conceptions that youth are digitally savvy, well-versed in all things digital and agnostic to what happens to their personal data are not supported by research.
  - While some youth may feel that their data is 'out there' and this is unavoidable [24,25], many studies find young adults want to be able to tailor access to their data and are concerned about data use and privacy [25–28]
  - There is a need for more information about the usage of youths' data, more education on data subject rights, and more choice for youth
  - Some research finds a lack of understanding about youths' rights as data subjects and of data sharing risks[24]
  - Other studies find youth want more clarity on how their data will be used (i.e., clearer terms and conditions)[26,28,29]
- Youth, like other age groups, harbour specific concerns regarding sensitive health data.
  - Mental health data is a specific area of concern for young adults[25,30,31], as is data on substance use and sexual health, which may carry specific concerns of access by the government or police[32]
  - Privacy concerns about health data vary by region and experience

○　Low-SES young adults report being more knowledgeable about risks of
　　　　　　sharing information online because of their concerns about privacy related to
　　　　　　systematic racism and classism in their day-to-day lives[33]

Box 8.a.1

Literature review method detail:

- Targeted keyword and forward and backward citation searching were used to obtain a formative understanding of the literature on youth's data privacy preferences
  - Health data - Anxiety and depression specific
  - Platform agnostic, but focused on digital data collection and use preferences
  - Regions - India, South Africa, UK
  - Individual differences such as suburban/rural, SES
- Studies were included if they could speak to youth specific concerns
- After reviewing abstracts, 24 studies were reviewed in full and 11 were included in the final review (six qualitative, three quantitative (survey-based), and two systematic reviews)

The workgroup discussed the feasibility and desirability of various methodological approaches and data collection schemes, settling on virtually-hosted deliberative democracy sessions (Appendix I.8.a.3) based on the need to seek pan-national consensus positions and the limitations on in-person gathering due to the pandemic. Key considerations included virtual platform fatigue ("Zoom fatigue") as well as platform features, such as technology access, platform usability, data load, and regulatory compliance (Appendix I.8.a.4 and Appendix I.8.a.5). The group discussed session cadence and scheduling, as well as approaches to educational provision, facilitation, power dynamics, and assessment of authenticity of participation, drawing on existing literature and grey literature for guidance in protocol development.

The group sought to maximise the diversity of youth contributing to the project. To this end, the workgroup planned two rounds of deliberative sessions (Figure 8.a.1): in-country and multinational sessions despite the focus of the funders on pan-national consensus positions. The purpose of the in-country sessions was three-fold. First, to allow for youth speaking languages other than English to contribute to the findings. Second, to ensure all youth had the opportunity to gain familiarity and comfort with discussion of data governance in advance of being
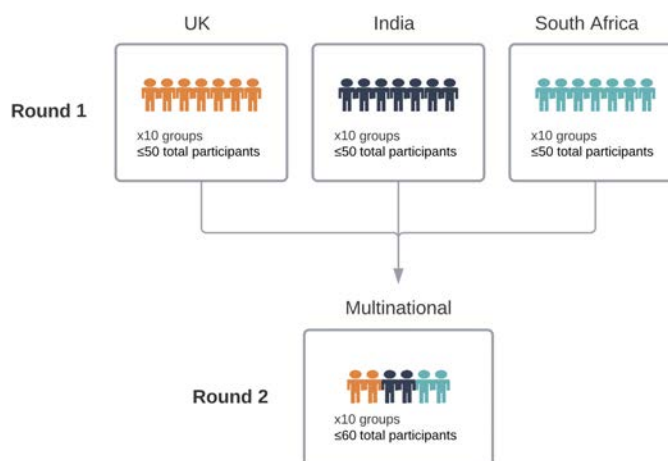
Figure 8.a.1: Round 1 (in-country) and Round 2 (multinational) deliberative session organisation.

asked to share opinions in a multinational setting. Third, to minimise power differences across youth participants from differently resourced countries. Sessions were further divided into "naïve" participants—those not concurrently enrolled in the quantitative study arm—and "co-enrolled" participants—those concurrently enrolled in the quantitative study arm to capture any differences between those youth considering data governance in theory versus those with lived experience of data governance for a global databank.

Figure 8.a.2: Data governance typology

Starting in September 2020 and extending through protocol development (Figure 8.a.3), the Sage team collaborated with the Professional Youth Advisors (PYAs) and consulted with the ad hoc International Youth Panel convened by the University of Washington and the India Youth Professional Advisory Groups (YPAG) (the South Africa and UK YPAGs were not yet running at the time of this consultation) to review the proposed methodology and approach. To refine the focus of the deliberative sessions, we consulted with both the YPAGs and the Data Usability Advisory Group (DUAG). Notably, prior to this engagement, Sage consulted with research regulation and legal experts internally and externally to assess the regulatory/legal compliance of various data governance approaches, further whittling the pool of governance options considered by the YPAGs and DUAG. The Sage team created a data governance typology (Figure 8.a.2) to facilitate meaningful input. These inputs were discussed with Wellcome at a Learnings meeting in January 2020 and summarised and published as a blog post in February 2021[34].
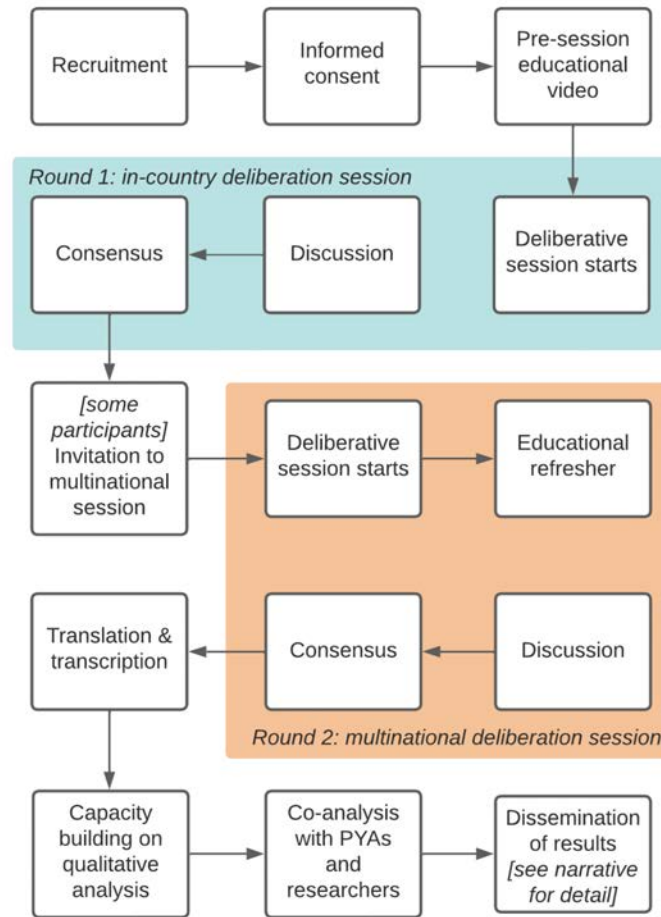
Figure 8.a.3: Overview of the Qualitative Study Arm

Learnings

- There are regulatory and legal hurdles that stand in the way of implementing specific data governance regimes for a global mental health databank composed of data contributed by youth. Wellcome might consider commissioning a legal review or engaging legal scholars to creatively assess the risk these hurdles might pose to an eventual global mental health databank. We limited the options presented to YPAGs and DUAGs.
- The qualitative study arm includes data governance models that Sage does not have experience in building; the quantitative arm only includes models that Sage has experience building/could conceivably host using its current tech stack. NB: Some of these models may not yet be mature, may limit the scope or types of analyses that can be done, and/or may limit researchers in some other way.
- Despite our extensive vetting of software platforms, we did not critically assess their ability to run on older computers/computing systems, for example, running older versions of Windows (and/or unknowingly running pirated/"free" versions of these systems) and/or the computer itself not having sufficient memory to support the platform. Providing technical support remotely is also, itself, very challenging. For international collaborations with countries of different resource levels, the interoperability and accessibility of the software needs to be our paramount consideration.

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b. Deliberative democracy educational provision

Approach

A standard component of the deliberative democracy method is providing participants with information, literature, or other materials to educate them on the research topic. During the initial information gathering phase, we identified three empirical studies that seemed to be most similar in topic, form, or participant population: McWhirter et al., 2014[3] and Secko et al., 2009[35], which solicited feedback on the development of biobanks, and Coleman et al., 2017[26], which elicited young people's opinions about their digital rights. It was evident from these sources that the mechanism of educational material dissemination would have to be highly adapted for our context, as these studies used plenary-style panels—and in the case of Coleman et al., dramatic storytelling—in order to convey information. Accordingly, we sought the assistance of YPAG panellists regarding both form and content for educational materials. As it pertains to form, we heard from panellists at all 3 sites that their maximum listening time without a break was approximately 40-45 minutes. Panellists also identified

technical issues as being a barrier to remote education, which many panellists had experienced during the COVID-19 pandemic. As such, we opted to record educational materials in mixed "Zoom-style" and animation formats and post them on Vimeo as downloadable video files rather than host plenary talks live streamed over Zoom. We felt that the downloadable video option would be better suited for our participants in multiple time zones with varying levels of internet stability.
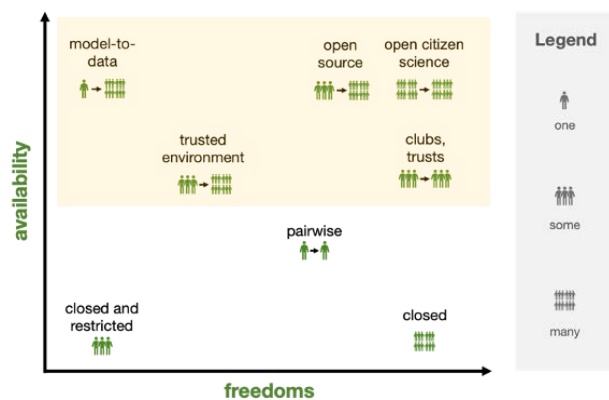
Figure 8.b.1: Potential Data Governance Models.

The foundation for the educational material presented was a Sage green paper on models of data governance[36]. At the request of Wellcome, we only pursued models with higher availability, such as those highlighted in Figure 8.b.1.
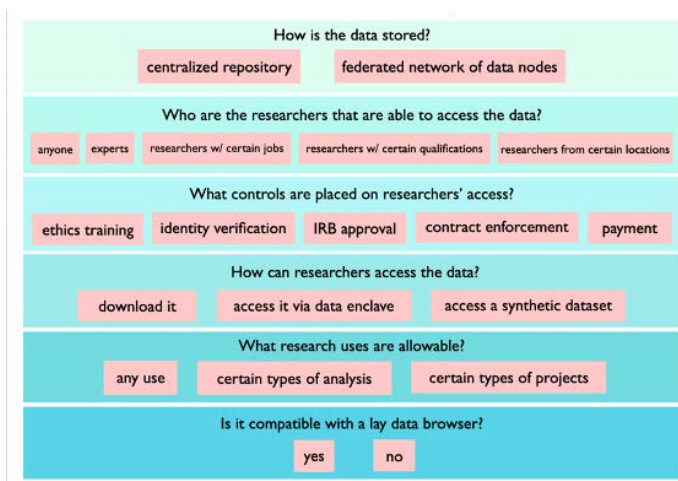
Figure 8.b.2: Original Version of the Data Access and Use Typology

Through additional conversations with the authors of the green paper and Dr. Jasmine McNealy at the University of Florida, who added a distributed autonomous community model to our consideration, we presented each governance model in a slide deck with advantages and disadvantages for each. We solicited written feedback on this deck from members of the DUAG and our colleagues at Sage. We used the feedback we received to update and refine our slide deck, also

introducing a governance typology (Figure 8.b.2), inspired by the insights of a tech team member at Sage, which became a cornerstone of our educational materials.

At the end of this iterative process with experts in the field, we had what we called internally a "professional" slide deck, a set of models with descriptions, advantages, disadvantages, and use cases that used standard industry language. We re-drafted this deck in more accessible plain language. The tools we used for this adaptation included: Sage's Elements of Informed Consent (www.sagebionetworks.org/tools_resources/elements-of-informed-consent/), Simple Wikipedia (www.simple.wikipedia.org), Hemingway app (www.hemingwayapp.com), and the *Wired* 5 Levels series (www.wired.com/video/series/5-levels).

We also renamed each of the data governance models after an animal that we felt embodied the characteristics of the model. The *open access model*, for instance, became the *peacock model*, where the data is displayed for all to see. While we were concerned that renaming these models with our own terminology would cut off participants' ability to seek out further information on these models for their own understanding, we recognized that many of these models do not have settled upon names even by professionals. The term *model-to-data*, for instance, is a term used by our own colleagues at Sage[37] and is not uniformly used in the literature. Conversely, we feared that terms like *model-to-data* and *distributed autonomous community* would feel unapproachable to participants. Accordingly, the resultant models and their analogous animal are presented in Figure 8.b.3.

Figure 8.b.3: Animal Model Options

We presented the plain language adaption of the "professional" slide deck to YPAG members and sought their preferences—which informed the choice architecture in the quantitative study—and their insights on which concepts were still unclear. After much back-and-forth, we also eliminated the *open access / peacock model* from consideration for youth participants because of concerns it would not be regulatorily feasible under GDPR.
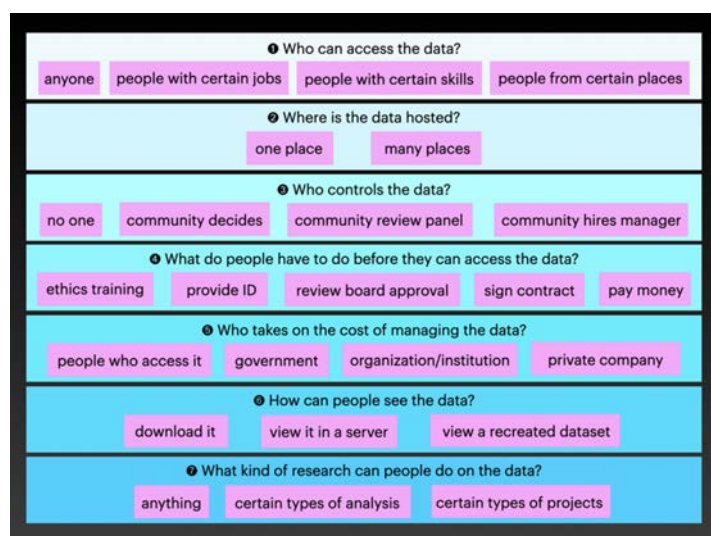
Figure 8.b.4: Plain Language Governance Typology

By way of comparison to the previous, the plain language adaptation of the governance typology is presented in Figure 8.b.4.

As we iteratively revised the language used in the slide deck, we wrote a corresponding narrative script. We opted to script each line in the educational videos so that the information would be identical at each site but could be recorded by each PYA to provide a more contextually relevant speaker for each site.

We also used animation to convey some concepts in the resultant educational modules. We sought an animation platform that would allow us to create customizable animations and ultimately used the website Animaker. We designed an animated figure for each of the three PYAs collaboratively and subsequently added two male study team members for increased gender diversity. We played and received feedback on video segments at various stages of development.

Because data governance may be rather unfamiliar to participants, we took seriously the possibility that our materials may make up the majority of participants' knowledge on the topic. In the absence of a surfeit of literature on what constitutes "fair" educational material for participants in deliberative democracy studies, we used our own internal standard that we called the *nail in the coffin* standard. In essence, we wanted to provide participants with legitimate choices; we didn't want the material to steer participants in a certain direction. As we enumerated advantages and disadvantages for each governance model, we strove to ensure that no one piece of information would nullify all others. One example pertains to the *distributed autonomous community / ant model*, which could use blockchain to store governance decisions. One disadvantage that is important to report is the potential energy consumption of such a model. However, we opted to stress to participants that energy consumption could vary based on how the model was built, not that this model was guaranteed to use as much energy as some costly instantiations, because we worried that the latter would constitute a "nail in the coffin" that would make this model so unattractive to participants as to not be a real choice.

The resultant educational materials are a two-module video series (Appendix I.8.b.1 and 8.b.2) with recording and filming contributions from the PYAs, additional study team members in India and South Africa, and a Wellcome Trust collaborator. We also developed an interactive concept map (https://stroly.com/viewer/1620332775/), inspired by our colleagues at ODI[38], to offer participants a more tactile way to engage with these materials. Design elements on the slides in the video and interactive concept map were done by a Sage design team member. A Sage governance team member wrote the copy for the interactive concept map. A Sage Applied ELSI Research team member wrote the scripts, made the video prototypes, and edited the videos.

Learnings

Educational Material Fidelity

We found strong fidelity across participants in relation to the educational materials. Our qualitative results indicate that these materials were, in general, widely consumed, widely understood, and accurately reiterated by participants. To encourage viewing the materials,

site teams planned to host "watch parties" over Zoom, where participants join and watch the materials together, but ultimately found these watch parties too challenging to schedule (UK) or too fatiguing after holding a few watch parties (India). The South Africa team hosted optional watch parties as well as used WhatsApp groups to remind participants of the materials' downloadability. Facilitators estimated that 80-90% of participants (India), 75% (South Africa), or 70-95% of participants (UK) did indeed watch these materials on their own time—although it should be noted that this is only an estimate based on participants' behaviour in deliberative sessions. Participants also made several direct references to viewing the material:

> *I chose the octopus model as my favourite one. I mainly liked the controls over the sharing of the data in the sense that,* **with the example one that was in the video**, *showing that people were* […] *able to access a base level of data just online, so anyone have that access, but for specific research access, it was more involved with what they wanted to do with it* […] *So, I didn't like the idea of putting the data behind a pay wall completely, or anything like that, because that felt quite restrictive in who could access that in terms of poorly-funded research, or whatever, might not have the resources. I guess the main issue with that model, though, is the fact that because it is so decentralised and it might be hard to know what you're going to need to provide when you're trying to access that data, because, say, if it's all from different groups, they might all have different requirements.*
> Participant 2, UK Session 1; referencing an example of the Beacon Network, a federated query platform for searching for genetic variants

> Mod 1: *So, viewing it in a recreated dataset, do you think that's something that you would want if it was your mental health data?*
> P2: *I guess it depends on the extent to which, I guess, it would impact the data itself.* […] **I remember in the video**, *it gave an example of two people's data being combined and averaging out their age, and stuff. And I guess it would depend if you had an 11-year-old and a 20-year-old, and their data got averaged out together, and averaged out their age, then, obviously, they both have very different experiences. So I guess there'd need to be something in place to make sure that only similar groups were combined for the recreated dataset, if that makes sense.*
> Mod 1: *You'd be worried about it distorting the data or making it too general?*
> P2: *Yeah, yeah.*
> UK Session 1; referencing the processes of a synthetic dataset, which involves mathematically representing the underlying raw data. The example given in the video was two unique individuals' ages being averaged.

> SAP15: *True. I think an organisation is acceptable, okay. And I think, for me, government is a maybe because if government pays for something, then they have the right to betray us,* **like in the first module**, *I saw the government of a certain country betrayed them and shared their information* […]
> SAP18: *I think it's a good point on that one*
> Moderator2: *So you also think it should be a maybe, or do you think it should be not?*

SAP18: *Funny thing is, she just said it the way I was planning to say **because watching those videos**. Simply says everything.*
South Africa Session 3; referencing a COVID-19 tracking app used in Singapore where the Singapore government shared some location information with the Singapore police force, despite publicly representing that they would not.

*So I think I feel that access to the data should be with people with certain skill sets. And that will probably include people with certain jobs too, because if we have, let's say, a comprehensive list of what all skills we're talking about, and if we have, like, let's say, a list of what all jobs we're talking about, we can include that in the list. And that just, you know, we'll come to both, but at the same time, I feel it's important, because when we're talking about research, **I am constantly thinking about the example that owl model had**. Feel that, when we give access to everyone, somewhere, what the results of these kinds of researches will be, will also be accessible by everyone, and then how people, you know, take this information and what they do with it, and how they present it later, will then be to their discretion. And when the general public sees that information, they'll believe it, irrespective of whether that person has the skills to even, you know, work on that data in the first place or not.*
Participant 10, India Session 4; referencing the example used in the *model-to-data / owl model* of a COVID-19 challenge where researchers submit computational models for detecting COVID infection to be run on a private dataset.

Not only do these comments make direct references to watching the material, but they demonstrate that participants seriously considered the advantages and disadvantages of different governance models and extrapolated use cases to their own context. We seldom found participants misinterpreting or misrepresenting the information presented to them. At times, participants may have swapped the names of two model types—in the last example, the participant may in fact be referring to the *ant model*—but these mistakes were of little consequence because the facts upon which participants made value judgments were well understood.

Comprehension Limitations

There were, however, limitations to these materials. Explaining the concept of a *synthetic dataset*, which we termed *recreated dataset*, was persistently challenging to participants and facilitators alike. This had been evident since the testing phase of the materials, and we attempted several analogies and representations with the YPAG members that were not well received. To be fair, however, synthetic datasets are an emerging concept even in the research community, and experts at Sage who work with these types of datasets also struggled to explain this to a lay audience. We also want to stress that despite challenges in understanding, participants' reflections on *recreated datasets* are not to be disregarded. Participants often expressed concerns that a recreated dataset would not accurately capture the underlying data (see Section 8.g "Deliberative Outputs"), which is a legitimate concern in the research literature[39].

Other areas that strained understanding were the option *community hires a manager* and the question *Where does the data live?*. The former, which was meant to represent when a data steward controls the governance of a given dataset, was often interpreted as one particular person managing the data rather than, for instance, an institution. Participants expressed concern that the data steward would become corruptible or overwhelmed with work (see Section 8.g "Deliberative Outputs"), often envisioning a single person controlling entire datasets. Again, these results are not to be discredited as a data steward role could be fulfilled by one individual—although not necessarily. Participants also raised sophisticated questions about who constitutes the *community*, which we represented in the educational materials as a research community (at times) or a participant community (at times) or a broader community of stakeholders. While questions about who the community is may pose challenges to deliberation, these are truly open areas of inquiry on which we welcomed participants to express an opinion. Additionally, despite the educational materials detailing how data "lives" in server rooms, which have a physical location, participants at times struggled to imagine this. When we asked participants for their preferences on where the data should "live," we at times received answers about cloud storage and the internet, overlooking the physical infrastructure that underlies these technologies.

Language Barriers

A more fundamental shortcoming of these materials is in their accessibility to non-English speakers. The materials were translated into three regional languages in India, and deliberative sessions were held in two regional languages at the India site. While all three site teams reported perceived high levels of understanding in their English-speaking participants—which were of mixed first- and second-language English speakers—the materials were not as successful among the non-English speaking participants. The India site facilitators noticed substantive differences in the nature of the clarifying questions asked by English-speaking versus non-English-speaking participants, with the former asking questions about sophisticated research processes and the latter asking more fundamental questions about concepts around data and research. The facilitators reported needing to make rather unrelated analogies that were germane to participants' everyday lives to bridge the understanding gap. A few reasons for this understanding discrepancy are proposed below:

- The original educational materials were written in English, based on research concepts largely published on and discussed in English. As such, the India team described these materials as being very challenging to translate into regional languages, either because equivalent terms did not exist or because they were not in everyday use to be comprehensible to young people. Moreover, the materials were translated into a more formal register of the regional language, which the participants found difficult to understand considering the novelty of the concepts.

- The non-English-speaking participants may have lower levels of exposure to technology and research. Even though we wrote these materials at the level of the average US 14 year old (eighth grade reading level or lower) in English, the concepts presented are still very sophisticated and perhaps better understood by participants who have some exposure to research studies, research data and related technologies. It is also important to note that the educational materials were developed by researchers who have intimate knowledge of these concepts.

- During the session, though the facilitators used a colloquial, everyday spoken form of the language, the participants had difficulty grasping the research (e.g., concept of a databank) and technology-related concepts (e.g., storage of data in servers). Through the interaction, facilitators realised that this was because participants were unable to relate the materials to their existing knowledge and context. When facilitators connected the concepts in the educational materials to technological concepts that the participants were exposed to in their everyday lives (e.g., privacy and personal data concerns when using social media platforms), they were able to comprehend and respond easily and subsequently participated enthusiastically.

Despite the relative challenges of the educational materials to non-English speakers, the data obtained from them offers rich depth and breadth to the Indian dataset.

Finally, it should also be noted that the educational materials were not translated into any major languages in South Africa other than English. Given our learnings with regard to Indian regional language translation, it may be reasonable to assume that translation into South African languages would be similarly labour-intensive and pose similar barriers in identifying the right framing.

Inflexibility of Video Leading to Content Drift

A disadvantage of video content is that it may not be able to flex to the dynamic nature of study design. Making a change in video is much more laborious than making a change in a document in Word. As such, some language and content drift occurred in relation to the video content. The consent flow in the quantitative study, despite being the product of the same initial slide deck as the qualitative study, used some subtle differences in language that may not be 1-to-1 comparable with the qualitative study. For instance, the app refers to a *volunteer review panel*, whereas the qualitative study refers to a *community review panel*. Because these options are slightly different, the qualitative study cannot be understood as a direct extension of the quantitative study. Furthermore, as we iteratively developed our facilitation protocol for the deliberative democracy sessions, we decided to take more of a "seven questions" based approach—using the data governance typology as the backbone of our protocol than a "four animals" approach—using the four animal models as our protocol foundation. However, of the two videos, Module 1 (approximately 12 minutes) is devoted to the "seven questions," and Module 2 (approximately 25 minutes) is devoted to the "four animals." As such, participants may feel that the educational content they received is not in proportion to the deliberative session they had. This disproportionality is almost entirely the result of the labour required to edit video content; with the material being written, audio recorded, video recorded, animated, represented in slides, and translated each time it is modified, making even minor changes to video content is highly time consuming. If the voice actors, animators, and video editors were an outside contractor without other study tasks to attend to, perhaps the editing process could have been more dynamic.

Recommendations

As effective as these materials were for their purpose in this study, a future project would benefit from use of an outside vendor that specifically works on making educational content. While Animaker was a useful platform for animated content, there may be research-backed recommendations on semiotic representations for concepts like privacy, security, and sharing. The semiotic devices used in this content, such as a lock to represent security, were

based on the creator's own design intuitions rather than industry best practices. Additionally, the two modules of approximately 12 and 25 minutes each, could be broken down into shorter video segments and hosted on an educational learning platform such as Canvas. While this recommendation was made by a communications professional at Sage prior to the launch of the study, we ultimately lacked the time and support to implement it. We were also concerned that hosting shorter video segments would require a consistent internet connection rather than a transient internet connection used to download longer videos and watch them offline. Researchers at Sage have also shown that, within the informed consent context, quizzes can be an effective strategy for reinforcing information.[40] This would be another useful inclusion to an eLearning platform.

However, given the more fundamental inaccessibility of this material to non-English speakers, in order for these materials to be approachable to participants with a range of linguistic, educational, and experiential backgrounds, more structural changes to these materials would be needed. A future designer could draw on the work of, for instance, the MIT-Haiti Initiative, which works with Haitian young people to develop "mother tongue books," children's books with examples that are more germane to their readers' lives[41]. More resources would also need to be devoted to translation, which was done in this context by just four individuals. Again, working with a professional vendor with demonstrated experience in accessible educational content would be beneficial.

c. Facilitation capacity building

Approach

We held a series of meetings to co-develop a facilitation protocol and to train facilitators to lead deliberative democracy sessions. The facilitators in this study were in a unique position; in traditional deliberative democracy studies, a facilitator is present to moderate the session and a content expert is available to answer questions about the educational materials. We decided to collapse these two roles so that each site team could have the flexibility of scheduling sessions in one time zone and on a rapid basis if needed. Accordingly, in a given session, the facilitation team is responsible for managing the technical logistics of the session, like admitting participants to the Zoom room and monitoring the chat; executing the facilitation protocol; working with a set of slides; building consensus on each question in the data governance typology; and answering content-based questions that participants had.

The Sage/UW team provided guidance on standard facilitation practices, including not sharing one's personal opinion, monitoring one's reactions, and asking relevant follow-up questions. We also asked each site to hold a "mock deliberative session" with their respective YPAG. YPAG members watched the educational materials and attended a two-hour session that operationalized the facilitation protocol. These mock sessions enabled facilitators to get a sense of timing and potential challenges during the session. Based on the mock session findings, we also made adjustments to the facilitation protocol before launching the study.

In their mock session, the UK team also tested a facilitation strategy that involved asking participants to classify the various options for each of the seven governance questions as *acceptable*, *unacceptable*, or *maybe*. This became a highly effective tool for revealing

disagreements and consensus building. We later standardised these slides and also offered the facilitation team slides that had space for taking live notes within the session if desired.

To train facilitators to answer content-based questions, facilitation teams consumed the same educational materials as participants. The source of their expertise was not different materials so much as sustained time, exposure, and dialogue regarding the governance options presented therein. Additionally, an unanticipated benefit of having the PYAs record the educational materials was that they were able to engage with the content in extraordinary depth.

To prepare for multinational sessions, our training was less related to facilitating sessions and answering content-based questions, on which facilitation teams were well-experienced by that time, and more centred around establishing our goals for multinational deliberation. In earlier discussions of Round 2 (multinational) deliberation, we had envisioned asking participants to represent the views of their prior session or even views of the youth of their country. However, after holding several Round 1 (in-country) sessions, we feared that asking participants to represent anyone other than themselves would produce unexpected or undesirable outcomes. For further contemplation on our method, see Section 8.g "Methodological Findings".

We incorporated other novel elements into the Round 2 (multinational) procedure. Each Round 2 session had three roles: lead facilitator, co-facilitator, and observer. The lead facilitator was tasked as the main driver and decision maker of the session, responsible for implementing most of the protocol. The co-facilitator was present to assist the facilitator in whatever way they saw fit, such as monitoring the Zoom chat, keeping track of time, or providing clarifications. The observer was present to pick up any remaining tasks. Each of these three roles was fulfilled by a different site team member per session, such that each Round 2 session had one representative from India, South Africa, and the UK. We used this strategy to ensure that participants from each country involved felt like they had an ally or a familiar face present in the session. We also encouraged facilitators in any of the three roles to prompt participants from their country to chime in.

Because we asked the same seven questions in the multinational sessions, we also shared back some information to participants to prevent a feeling of redundancy. We directed the facilitation team to use framing devices such as, "This is an area where UK and Indian participants really disagreed at the in-country level; what do you think?" As much as possible, site teams also attempted to invite participants from different in-country sessions to a given multinational session. This was one of a couple changes we made after hosting the first multinational session and observing participants' interactions.

An additional update we made to the multinational approach was a new "icebreaker," which was about the 2021 WhatsApp privacy policy change[42]. While in Round 1 (in-country) sessions, we were hesitant to introduce commercial stories of data governance (gone wrong) because we didn't want participants to conflate commercial data use with research data use, we felt that at the multinational level, one prior round of deliberation was a sufficient foundation to engage with commercial data (mis)use. Figure 8.c.1 demonstrates the slide we used to frame this topic.

We asked the following probing questions: (1) What effect does this have on users? (2) Does this change affect people around the world equally? Does it affect some people more than others? (3) What does it mean that other apps like Signal and Telegram gained so many users in response to this change? What does that say about users' values?

Icebreaker: WhatsApp Privacy Policy

- In 2021, WhatsApp added new communication with users to clarify that they will share account information like phone number, IP addresses, and device identifiers with Facebook.
- WhatsApp has had this in their privacy policy since 2016, but it became more clear to users when WhatsApp began notifying users about it in 2021.
- WhatsApp also announced that if users do not agree to this policy, they will have limited functionality.
- Days after this announcement, messaging apps Telegram and Signal gained millions of users.

Figure 8.c.1: Icebreaker on the WhatsApp Privacy Policy.

This icebreaker was highly effective. Participants almost to a person recalled the WhatsApp privacy policy event and shared how they and their friends responded. While we did not analyse participants' responses to this prompt as it did not tie directly to the outcomes of this study, this icebreaker was extremely effective at elucidating how participants situate themselves in the commercial tech landscape.

We updated the protocol a final time to add a terms of use document (Appendix I.8.c.1) and safeguarding protocol. This document, meant to be disseminated to participants prior to their multinational session, offers participants some terms and definitions that may be useful to them. While participants were largely respectful to the positionalities and experiences of others, they at times used language that may be offensive (e.g., "third world countries"). We did some additional training with the facilitation team to prepare them to model more appropriate language use, and we prepared for the possibility of a participant using overtly derogatory language. While the latter situation did not ultimately occur, the preparation was a useful endeavour.

In order to harmonise different site-specific facilitation styles prior to a given multinational session, we implemented two measures: (1) We held a 30-minute "tech check-in" prior to the start of the session where the lead facilitator, co-facilitator, observer, and a member of the Sage Applied ELSI Research Team went down a checklist of items, ensuring that captions were working, that Zoom hosts were appropriately assigned, and that facilitation preferences were discussed. (2) We also agreed as a group to yield to the lead facilitator of a given session. In other words, if the lead facilitator preferred to take live notes and one ten-minute break, the other facilitation team members worked to ensure this.

Learnings

The preparation for deliberative sessions was largely well-received. All three teams found the mock deliberative session to be particularly useful. The PYAs, having also facilitated several meetings with YPAG members, also attested to how that facilitation skillset assisted them in deliberative sessions. The India team, however, felt they could have benefited from some additional preparation prior to the first session. In terms of capacity to answer content-based questions, all three teams felt mostly prepared but reflected on the utility of

having multiple trained facilitators present in a session in case the lead facilitator wants to pass on the question. Indeed, in South Africa, lacking a set of trained, "backup" facilitators posed persistent issues to data collection. To fill this facilitation gap, a member of the Sage Applied ELSI Research Team joined the final two South African in-country sessions. Having a facilitator present who lacks the cultural and national background of participants is, of course, not preferred. The challenges presented by the absence of staff redundancy then permeated into the multinational level, where a member of the Sage Applied ELSI Research Team facilitated a few sessions as a stopgap measure. The multinational sessions, because they involve incorporating four teams across four time zones, have little flexibility for facilitators falling ill, losing their internet connection, or running late. Accordingly, a member of the Sage Applied ELSI Research Team was an "on call" backup.

Recommendations

Given the utility of the mock sessions, doing more than one mock deliberative session may have been a helpful additional step. Another training tool could involve one trainee facilitator leading a mock session to a group of other facilitators, who could assess their performance and ask challenging content-based questions. Additionally, in a study of this size, having a set of backup facilitators who can fill in on short notice is an ideal setup.

d. Recruitment

Recruitment approaches differed for app naïve participants compared to co-enrolled app users for all sites. The recruitment for the naive sessions were swift for all, with sites reporting the effectiveness of emails to personal networks and partner organisations. The participants who joined the deliberative democracy sessions were all then invited to share the opportunity to participate in the sessions with their peers and in their social networks. This snowball strategy was also reported as effective. In contrast the co-enrolled participants received a pop up with site specific links to join the study. Due to technical issues, some South African participants failed to receive this in app notification as expected which meant that their recruitment of these participants were different. The effective and challenging aspects of recruiting co-enrolled and app naive participants to the deliberative democracy sessions are detailed in the sections below. Tables 8.d.1-8.d.4 display recruitment totals for each site and at the multinational level.

India

Recruitment for app naïve participants

In contrast to the quantitative arm, a more targeted approach was used to recruit the naïve participants for round one of the deliberative democracy sessions. To ensure diversity in the participants, the team reached out to youth-based organisations working with non-English speaking youth populations in urban and rural contexts. Emails, WhatsApp messages, and personal connections were used to connect with youth for this arm of the study (Appendix I.8.d.1, page 1). Additional information was provided over a phone call with the research team.

Table 8.d.1: India Site Recruitment

	India		
Session No.	**Group Age**	**Enrollment Status**	**Attendee No.**
1	21-24	naïve	7
2	18-20	naïve	6
3	21-24	naïve	5
4	18-24	naïve	7
5	21-24	co-enrolled	5
6	18-24	co-enrolled	5
7	18-24	co-enrolled	7
8	21-24	co-enrolled	4
		Total naïve	25
		Total co-enrolled	21
		Total	46

Table 8.d.2: South Africa Site Recruitment

	South Africa		
Session No.	**Group Age**	**Enrollment Status**	**Attendee No.**
1	18-20	naïve	6
2	21-24	naïve	6
3	21-24	naïve	5
4	21-24	naïve	3
5	21-24	naïve	9
6	21-24	co-enrolled	2
7	18-20	co-enrolled	14
8	18-24	co-enrolled	7
		Total naïve	29
		Total co-enrolled	23
		Total	52

Table 8.d.3: UK Site Recruitment

	UK		
Session No.	**Group Age**	**Enrollment Status**	**Attendee No.**
1	16-17	naïve	3
2	16-18	naïve	4
3	19-23	naïve	3
4	19-23	naïve	7
5	16-18	naïve	5
6	16-18	co-enrolled	4
7	16	co-enrolled	2
8	18-19	co-enrolled	2
9	19-22	co-enrolled	4
10	19-22	co-enrolled	4
11	18-23	co-enrolled	7
		Total naïve	22
		Total co-enrolled	23
		Total	45

Table 8.d.4: Multinational Site Recruitment

	Multinational		
Session No.	**Group Age**	**Enrollment Status**	**Attendee No.**
1	21-24	naïve	5
2	16-20	naïve	3
3	21-24	naïve	8
4	16-20	naïve	7
5	16-20	naïve	5
6	16-20	co-enrolled	6
7	16-20	co-enrolled	7
8	21-24	co-enrolled	7
9	21-24	co-enrolled	13
		Total naïve	28
		Total co-enrolled	33
		Total	61

SageBionetworks

Recruitment for the co-enrolled participants

For the co-enrolled participant recruitment, the team primarily relied on the pop-up notification on the MindKind study app which directed interested participants to sign up for the qualitative study. However, only 8 participants were recruited through the pop-up message.

The team decided to contact participants who had signed up for the MindKind study app to reach our recruitment target. The team made a phone call to the participants enrolled on the app to explain the qualitative study protocol and followed it up with a text message with details on how to sign up. In case the calls were not received, direct text messages were sent with details about the qualitative study. The team attempted to contact 220 participants in total, out of which 22 expressed interest in the study and completed the sign-up form. Of the 22, only 13 participated in the sessions.

Twitter and Instagram posts were also used to invite MindKind study app participants to sign-up for the qualitative study (Appendix I.8.d.1, page 2). This did not lead to increased sign-up for the qualitative study.

Recruitment for the multinational participants

In the application form of the qualitative study, the team requested to record their interest to participate in a multi-national session. After each in-country session, participants who were engaged in the discussion, and had expressed interest in multinational sessions were contacted and invited to participate in the session.

South Africa

Eight deliberative democracy sessions were held with South African participants, following the process described above. The participants in five of the sessions were naïve, in that they were not enrolled to use the App. The final three sessions had participants that were co-enrolled–they were or had been performing the App tasks and were recruited for the qualitative arm. In total, 29 participants took part in the naïve sessions, and 23 in the co-enrolled sessions.

Recruitment for app naïve participants

Participants were recruited through two social media platforms (WhatsApp and Facebook). Participants were informed on the nature of the sessions, the educational materials to be consumed beforehand and the amount of data that they will receive in order to participate without any hindrance.

Recruitment for the co-enrolled participants

Co-enrolled participants were recruited through the pop-up message that was designed for the app users to see and be redirected to the MindKind South Africa email account where they can express their interest. Similarly the same message was used on WhatsApp for all the co-enrolled participants that were actively raising queries on airtime requisition.

Recruitment for the multinational participants

Before the end of each local session participants were asked to volunteer to be a part of the multinational sessions; volunteers would then be grouped on WhatsApp according to their age groups for effective communication on the dates and times of these sessions.

The South African participants consisted primarily of university and technical college students from low socio-economic backgrounds. With the COVID-19 pandemic, most of these institutions largely shut down and conducted teaching using internet platforms (e.g., Zoom, MSTeams, Blackboard, etc.). Students dispersed to homes in townships or in rural areas. Internet access and WiFi is generally available to students when at their institutions, but when these were locked down, students had to rely on using data/airtime with their smartphones. This form of internet access is expensive, as well as unstable.

UK

Recruitment for app naïve participants

Emails were sent to individuals who had applied to be a part of the YPAG and agreed to be contacted about future research opportunities. Participants who replied indicating that they were interested in taking part in deliberative democracy sessions were sent a JISC survey to complete with their demographic information. Other app-naïve participants were largely recruited via posting recruitment materials to our own networks (e.g., using departmental Twitter and Instagram accounts) and placing posters in our local communities in Cambridge, Oxford and Kent. Interested participants emailed a member of the project team, and were then sent the same JISC survey to complete. Young people who participated were told it would be great if they could let their contacts know about the opportunity, and little further advertising was needed.

Recruitment for the co-enrolled participants

Those who had used the MindKind app were directed to the JISC survey via a pop-up notification. Those who were interested completed the JISC survey and were then contacted by a member of the UK study team.

It was harder to recruit co-enrolled participants, as so many who completed the survey saying they would like to attend did not respond to follow-up email contact. Those who did attend from the co-enrolled group seemed a little less concerned about privacy issues than those from the naïve group, and sometimes seemed to have more scientific literacy.

Recruitment for the multinational participants

After in-country sessions, participants were asked if they were interested in participating in multinational sessions. Those who were interested were sent a doodle poll to indicate their availability for the sessions. A member of the study team allocated participants who completed the doodle poll to an appropriate multinational session. Where participants did not attend, they were usually contacted once more to see if they wanted to attend a different session.

Learnings

India

For naïve participants, repetitive follow-ups were needed to ensure that the team could get access to youth from marginalised communities. The team had difficulty recruiting bilingual speakers from the marginalised communities which was a requirement for the multinational sessions. This was in addition to resource challenges of not possessing a smartphone, and data related challenges of no stable internet connection.

India site enrolled participants on the study app primarily from February to March 2022, this reduced the number of participants exposed to the pop-up notification (two weeks post enrolment) in the overlapping qualitative recruitment window, February to March 2022. Perhaps this contributed to a low response rate (8 sign-ups) on the co-enrolled participant response on the study app.

Reaching out to study app participants via phone calls and text messages was a resource intensive strategy for a low conversion rate. Out of 220 phone calls followed up by text messages, only 13 participated in the deliberative democracy sessions. Nevertheless, it helped the team reach the required target in time.

South Africa

Human error delayed part of the data collection in that the telephone number used to generate text messages to the participants inviting them to join the next part of the study was recorded incorrectly, resulting in delays when it came to effective recruitment. Frequent research team meetings helped to identify snags and address the issues as they arose following the identification of the specific challenges listed above.

The research team also faced a challenge of the participants indicating they could not join any of the cross country or Youth consultation sessions because they needed data loaded beforehand in order to do so. When data was loaded before the sessions however, some of the participants who had already received data, did not take part as promised. The approach there was to feedback this challenge to the participants and agree with them that the best solution which would be fair to everyone was for them to join the session and contribute first and then receive the remuneration of the data afterwards.

The issues of giving data to participants before the sessions proved to be quite a challenge as some of the participants ended up not attending the sessions and some switching their phones so that we do not get hold of them.

UK

Recruiting co-enrolled participants was a challenge especially because the UK was able to recruit younger participants due to the lower age of majority (aged 16-18), resulting in a third band of age stratification. This meant the team had a smaller pool to recruit from for each session. For every eight participants contacted after they signed up, only one ended up completing consent and attending a session. As a result, assuming equal numbers in each age stratification, to have five participants in each age group required 120 app users to sign up. It would then be a case of arranging a time for each session that all five participants in

that age band could attend. This had three main consequences. Firstly, to arrange each of the focus groups was extremely work intensive and time consuming, and most of those who initially signed up did not go on to attend. Secondly, the team had to be flexible with age ranges to maximise the number of attendees at each session whilst continuing to ensure that 16-18 year olds were not in sessions with 24 year olds. Finally, when fewer than fine participants showed up to a session, the team decided to go ahead so as not to disappoint those who had attended. Despite some sessions having fewer participants than planned, the UK team reported no impact on their in-country analysis. The UK team found that the range of views and breadth of discussions were similar regardless of the group size, at times enabling participants more time and space to express and discuss their beliefs and experience in the smaller groups. Furthermore, it is important to compensate participants who have set time aside to attend sessions, rather than turning them away due to low numbers.

In addition, since–uniquely to the UK–the younger participants were still of compulsory school age, it was difficult to recruit them for Round 2 (multinational) sessions that were scheduled at 12-2pm (GMT) to accommodate multiple time zones. However, when these sessions were held during the school half-term break, it was easier for younger participants to attend.

Recommendations

India

Adequate space and time should be provided to ensure diversity of participants, especially for a feasibility study. In-person sessions to increase the reach to marginalised communities could be considered in the future.

Honorarium for participant's time and effort was an important ethical responsibility that was possible in this study and should be continued in the future.

South Africa

To enable participants to join the deliberate democracy sessions, the South African researchers provided the participants with data/airtime. Of the 2 sites in SA, WSU was the most rural and was often the most affected by connectivity challenges, making the participants even more dependent on receiving the data prior to the engagement sessions. Distributing the data beforehand and still managing to ensure that participants showed ongoing engagement in the data collection after the data has been received was a real challenge.

The approach taken was to discuss the challenge openly with participants and to agree on the best solution to apply which was the "connect first then receive data" approach. This meant that participants received data only once connection to the next session had been done successfully. This worked better at ensuring participation and retention, with better commitment to connecting for sessions. However in some cases it was still necessary to give phone data beforehand as participants did not have any funds to join unless they were remunerated for the data time beforehand.

The terms of agreement for participation in the deliberative democracy sessions was explained prior to an ice-breaker. This was used to allow participants to feel comfortable with their peers. The terms of agreement would include ground rules and direction on how to use Zoom features including the chat function.

UK

It is worth considering whether stratifying groups by app-experience is important, because it was difficult and labour-intensive to recruit the co-enrolled group, and the benefits of doing so were unclear. Whilst having a diverse set of participant experiences is certainly important, stratification on this basis, with the benefit of hindsight, contributed little. Mixing the co-enrolled and naïve groups would have allowed for more flexibility and made recruitment easier.

e. Data collection process

Approach

Our two-round data collection design is shown in Figure 8.a.1. Each site held Round 1 (in-country) deliberative sessions with approximately n=50 participants per site (actual sample sizes are in Tables 8.d.1-8.d.3). Of these 50, approximately n=25 were not enrolled in the quantitative study ("naïve participants") and n=25 were enrolled in the quantitative study ("co-enrolled participants"). A subsection of these n=150 total Round 1 participants participated in the Round 2 (multinational) sessions, which had a sample goal of n=60 with approximately equal participation from each site (actual sample size is in Table 8.d.4).

Sessions were approximately 2 hours each, held over Zoom. Participants used a range of communication modalities within the session, including audio/video participation, writing in the Zoom chat, and using the "thumbs up" function and other emoji reactions. At the South African site, participants also occasionally added thoughts over WhatsApp when they experienced a loss of internet connection. In addition to the seven data governance questions, which was the most dominant topic of the session, sessions also included an icebreaker and "ground rules" and three polls: (1) Pick your most preferred "animal model." (2) What is your most important organising question from the discussed 7 questions? (3) What is your least important organising question from the discussed 7 questions? If facilitators were pressed for time, teams generally either asked participants for additional time or did not discuss all seven questions. Polls (2) and (3), as these were conducted at the end of the session, were also often skipped for time.

While consensus was sought in each session, the specific mechanisms for doing so slightly differed from site to site and at times facilitator to facilitator. Facilitators moved question options between *acceptable*, *unacceptable*, and *maybe* based on the discussion. When discussion seemed to converge, the facilitator generally asked participants to ratify the current distribution of *acceptable*, *unacceptable*, and *maybe* on screen. Participants gave verbal affirmation, wrote in the chat, used emojis, or used the "hand raise" function to agree. If the facilitator felt that participants were not going to agree, or if there was not enough time to seek consensus, they generally stated that consensus would not be reached on a given question and moved on. However, facilitators had different thresholds for moving on. What if 6 of 7 participants give a thumbs up but one doesn't make any gesture? Is this a consensus?

The answer to this question was facilitator- and context-specific. Accordingly, Figures 8.g.1-8.g.4 exhibit trends in *acceptable*, *unacceptable*, and *maybe* groupings, not 1-to-1 relationships with numbers of participants assenting and dissenting.

Notwithstanding subtle stylistic differences, facilitators on the whole engaged in open dialogue about the consensus-building process. Facilitators made statements like: "Based on what [name] said, I'm moving *many places* from *acceptable* to *maybe*." When consensus was not reached on a given question, facilitators would inform participants: "I don't believe we'll reach consensus on this question, so I'm going to move on." Facilitators also often summarised participant statements and invited participants to disagree: "What I'm hearing is that you are concerned about privacy—is that accurate?" In the style of consensus-based deliberative democracy research, the deliberative outcomes were meant to be recognizable to participants.

Learnings

There were several challenges posed by the form and method of the qualitative study. Like in any focus group-based study, scheduling a quorum of participants for a time slot is not a simple task. Scheduling itself requires resources, patience, and persistent follow-up with participants. Even still, small sample size was a frequent issue. For the Round 2 (multinational) sessions, for instance, we implemented a sample threshold to make sessions worth our while, which was 1 participant per country. Regrettably, when we did not reach this threshold, we had to either reschedule without advanced notice or even reschedule participants who had already shown up to join the session. Indeed, the logistical challenges presented by scheduling are compounded in the multinational session context, where we were negotiating three time zones (plus a fourth from the Sage Applied ELSI Research Team member who was on standby). The standing time we ended up using was 7am ET (US) / 12pm GMT (UK) / 2pm SAST (South Africa) / 5:30pm IST (India). As such, our participant population was limited by who was available during these times.

The length of the session, despite being relatively short by deliberative democracy standards, could be tiring for participants and facilitators alike. Translating a traditional deliberative democracy study, where participants meet over a weekend in a conference space with frequent meal and coffee breaks, to the online context was a challenge. Even at this compromised length, the vibrancy of participants often dropped off toward the end of the meeting. Facilitators were also challenged by fitting the protocol into the allotted time.

The online context had other unique effects. Participants' sound quality was frequently compromised by background noise, connection deterioration, or mistakes with the "mute" / "unmute" function on Zoom. Participants and facilitators experienced "Zoom fatigue," and many participants engaged only in the chat box. While the chat function may have also been useful to participants for a variety of reasons, sustained chat use at times produced the effect in the written transcript of a facilitator appearing to have an extended conversation with themselves—reading out the chat and responding in kind. At times participants also seemed to be not present despite having joined the Zoom call—perhaps engaging in other activities instead. This dynamic makes it difficult for a facilitator to evaluate their own performance, as it can be unclear whether silence is a sign of discomfort, acceptance, or just absence.

This challenge became compounded in the multinational sessions, where we were coordinating across several teams. There were several participants who joined the Zoom call and did not contribute to the conversation, leading to conversations between facilitators about what the participant's situation was, whether we could contact them, et cetera. Participants also sometimes borrowed a device to connect to Zoom, and the name displayed on Zoom may not be the participant's name, leading to some confusion and scrambling to understand the situation.

Conversely, the obvious advantage to remote data collection was the ability to safely conduct deliberative sessions in a pandemic context. This advantage of course cannot be overstated. There were participants in our sample with clinical vulnerability to COVID-19 and participants who were caretakers for others who may have been excluded from in-person sessions. Facilitators also noted the utility of working from home when sessions were conducted outside regular working hours. Not needing to commute to a data collection location offered facilitators more flexibility. The remote approach also enabled us to reach participants in geographically distinct locations, both within a given country and in multinational sessions. Participants shared really positive reflections on the opportunity to talk to participants in other countries. In Multinational Session 2, for instance, which was live-translated between participants of different linguistic groups, a participant shared at the end of the session:

> *I would also like to say something. We felt very nice, that is we got to do something new and that we are attending the international meeting for the first time. We had a problem with English, that is, the language, but still, the opinion of all of us turned out to be similar, and it felt very nice to have a meeting with you. I feel that we are like a family, a family. Thank you.*

Indeed, despite some difficulties, participants who offered statements at the end of the session or filled out the exit survey gave overwhelmingly positive feedback on fairness, inclusion, and the opportunity to hear from peers (See exit survey data in Section 8.g "Quality Assessment").

Transcribing multi-modal data also presents a set of unique challenges. For focus group data collected remotely, the most ideal transcript incorporates the chat dialogue into the spoken dialogue. However, in our experience, there are few resources available for this, and few transcription companies are willing to do this. For instance, we worked with two transcription vendors on the multinational transcripts, and both were unwilling to incorporate the chat in a time-based manner. As such, those transcripts (in-country) that have chat incorporation were done manually by study team members, which was a particularly arduous process. More guidance in the literature about synthesising multi-modal data is needed.

Recommendations

There are more regimented ways of seeking consensus where every single participant is accounted for, if desired. For instance, a basic tally could be taken of how many people agree that a certain option is *acceptable*. An alternative in the online domain is to hold a poll after every question asking how many participants agree with the *acceptable*, *unacceptable*, and *maybe* distribution on screen.

The standard for chat incorporation was set by the UK team, who incorporated chat statements based on the timestamp of the chat record, which was cross-referenced with the timestamp on the video recording. The colour of chat statements was changed, as these statements may have typos or emojis that are not used in speech. This method was effective at providing the full picture of participants' views. Zoom recordings unfortunately do not store emoji use, hand raising, or a video feed of any participant who is not currently speaking (e.g. a participant offering nonverbal cues). The most representative recording/transcript would keep all this information, as it all informs the discussion.

f. Analysis approach

Deliberative & Analytical Outputs

There are two primary outputs of deliberative democracy processes: deliberative outputs and analytical outputs[43]. *Deliberative outputs* are statements of consensus or disagreement that arise directly from discussants. These consensus-based outcomes were captured by the facilitator and ratified by discussants themselves before the end of their session. In our context, the findings that constitute the deliberative outputs of this study are the ratified, consensus-based options that participants chose and their primary arguments for choosing these (see Section 8.g "Deliberative Outputs"). These arguments are distinct from the *analytical outputs* in that they are explicitly recognizable; all we have done is summarised participants' quotes. These arguments were also commonly made—which is a fraught concept for qualitative research—but we did not include arguments from one participant at one session only.

Analytical outputs are derived from the qualitative analysis process. We employed the framework method[44] to capture analytical outputs regarding concerns, hopes, and expectations of discussants for a prospective global mental health databank. These findings are described in Section 8.g "Analytical Outputs." For a complete analytical framework in the style of Gale et al., 2013[44], see Appendix I.8.f.1. The process we utilised to train and scale up for qualitative analysis (to capture analytical outputs) follows.

Training & Analysis Preparation

An overview of our process for training, framework development, and qualitative coding is provided in Figure 8.f.1. Data from the deliberative democracy sessions were collaboratively analysed by all three study sites with the support of the UW/Sage team. Each site participated in several qualitative analysis trainings to support them through the process. Every effort was made to ensure the raw data were reviewed and analysed by the site researchers to protect the contextual validity of the data and to minimise misinterpretations of the data. In addition, we wanted the final framework to be informed through emergent data stemming directly from the research sites.

The framework development was informed through an emergent thematic analysis. A modified, collaborative, thematic analysis used previously by Björling, et al. 2020[45] was

implemented to ensure contextually rich data emerged from the individual study sites and directly informed the framework.

The analysis procedure was informed by Clarke et al., 2015[46] (early stage thematic development) and Gale et al., 2013[44] (later stage framework development). We followed the following primary stages of thematic analysis prior to framework development: (1) familiarisation with the data (reviewing transcripts and recordings), (2) extraction of excerpts (identifying salient discussions and excerpts), (3) collaboratively coding of the extracts (discussion of excerpts with the site researchers and determination of emergent codes), and (4) conceptualisation of themes (relationships among the codes). However, these stages involved collaboration within sites and within the project.

Figure 8.f.1: Training and Framework Development Process

Familiarisation with the Data

Site researchers reviewed transcripts and recordings to refamiliarize themselves with the data. Research teams divided the data among them and each were responsible to review a portion of the site's data.

Extraction of Excerpts

Individual site researchers reviewed transcripts with the intention to extract salient/meaningful data. Quotes were extracted and placed in a shared spreadsheet for review by UW/Sage researchers. Note: Given specific circumstances for the South Africa site and the requirement to ensure emergent data were identified by site researchers, UW/Sage researchers provided support to the research staff in this process.

Collaborative Coding

Site excerpts were reviewed and discussed by UW/Sage researchers and preliminary emergent codes were developed to represent the data from all sites. These preliminary codes were then reviewed and discussed by site researchers. This discussion led to a slight modification and clarification of the various codes.

Conceptualisation of Themes

From the excerpts extracted by each study site, the UW/Sage team then developed themes that illustrated relationships between excerpts.

Phase 1: Emergent Coding

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The UW/Sage team reviewed all excerpts extracted by the site researchers, which was collectively approximately 110 sections of text. We then collaboratively explored these excerpts and organised them into larger themes and supportive emergent codes.

Phase 2: Framework Development

Two tensions emerged immediately: *control the data & access* versus *can't control the data access* as well as *benefits* versus *risks of data sharing*. These tensions were highlighted and became the main themes of the framework (Figure 8.f.2) supported by thematic codes stemming from the emergent excerpts. The framework and associated codes were then shared with researchers from the three study sites for review.
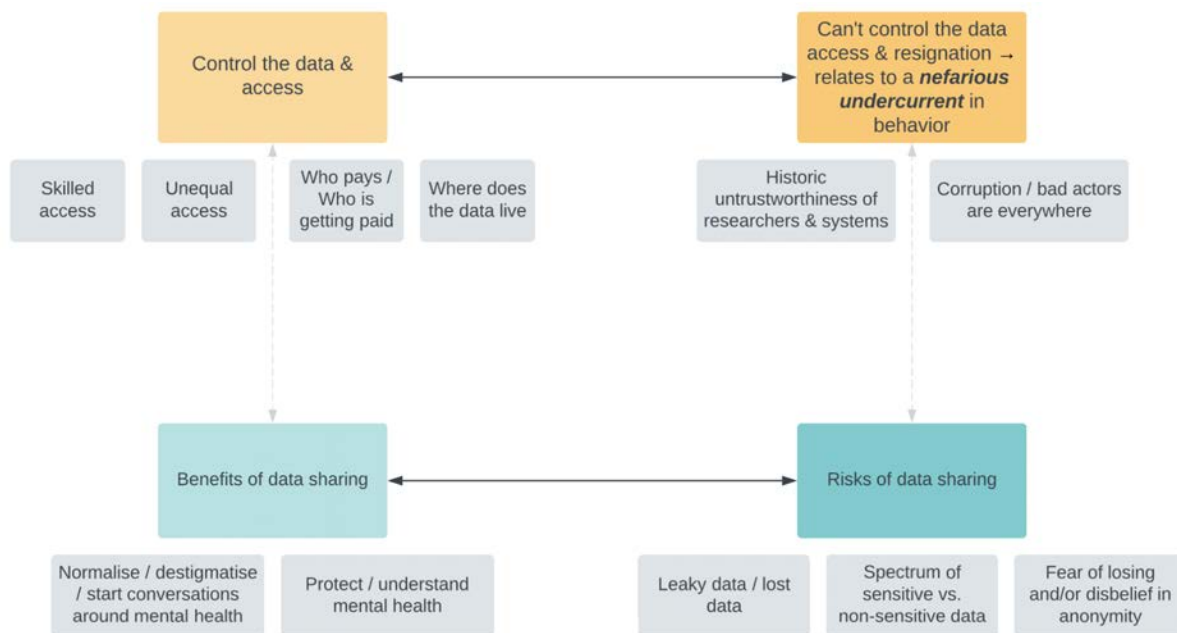
Figure 8.f.2: Analytical Framework

After confirmation of the framework by the three study sites, the UW/Sage team replicated the excerpt extraction and thematic analysis process with the multinational data. As expected the multinational data also fit very well into the framework and its associated tensions and codes.

Learnings

Upon review of the framework by the site researchers, some code definitions were clarified based on site input. In addition two new codes were added to further illustrate the range of data under each tension. Under the control vs. can't control the data spectrum, the code of *unequal access* was added to illustrate the many ways in which inequality might affect access to the data. In addition, under the benefits versus risks tension, *spectrum of sensitive vs. non-sensitive data* was added to represent excerpts in which participants discussed how varying types of sensitivity may affect data sharing risks. In the end, all site researchers felt the framework represented the data shared by participants. Finally, we found some methodological themes that emerged while exploring the multinational data and identified

those themes (discussed in Section 8.g "Analytical Outcomes") as "learnings" related to the process.

g. Results

Findings

Deliberative Outputs

Figure 8.g.1 exhibits the aggregate deliberative outputs on the seven governance questions. Note that the Y-axis captures both acceptability and level of consensus. Accordingly, options that were acceptable to participants and widely agreed upon are clustered near the top. Options that were unacceptable to participants and widely agreed upon are clustered near the bottom. Options that posed significant disagreements, often leading to a lack of consensus are clustered near the middle. These options may have achieved consensus (as acceptable or unacceptable) in some sessions but not many. Given the variation in consensus-taking by facilitator, Figures 8.g.1-8.g.4 were derived by reviewing acceptable, unacceptable, and maybe groupings, and by discussion among facilitation teams. Figures 8.g.2-8.g.4 demonstrate findings for Round 1 (in-country) sessions in India, South Africa, and the UK.
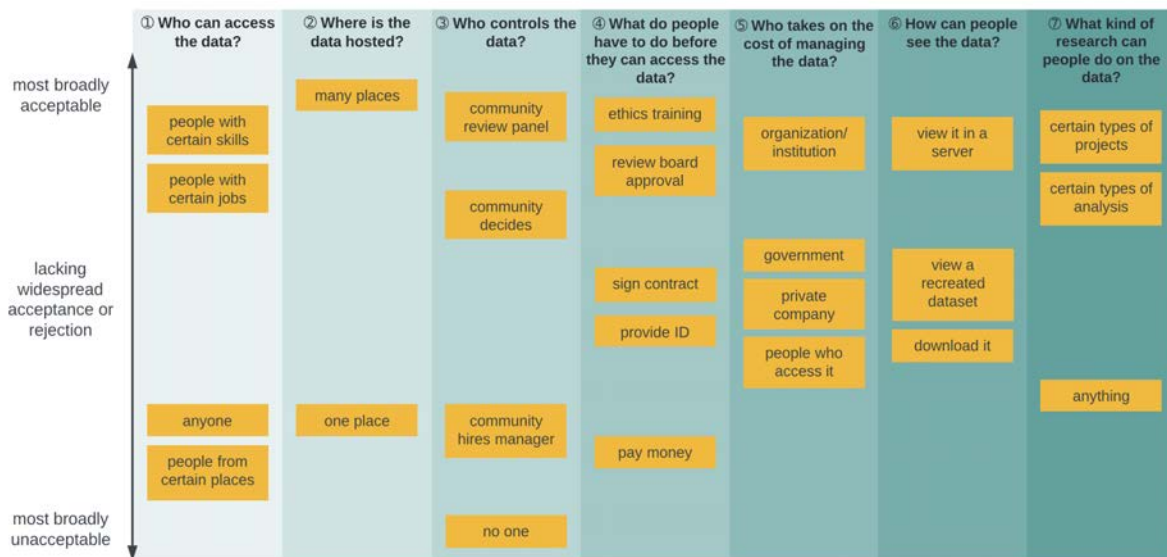
Figure 8.g.1: Aggregate Deliberative Outputs
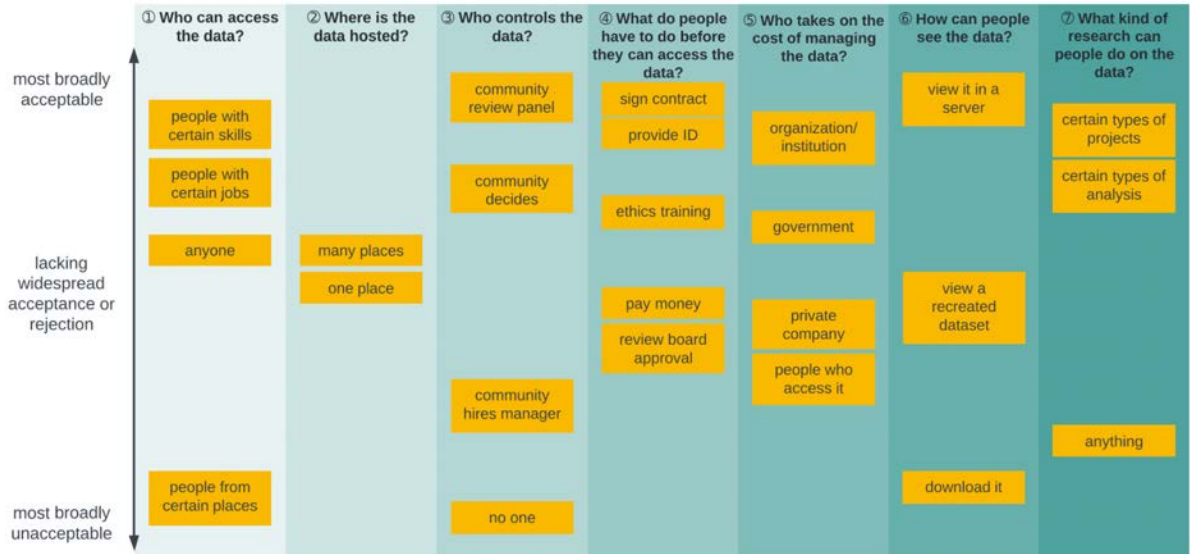
Figure 8.g.2: India Site Deliberative Outputs
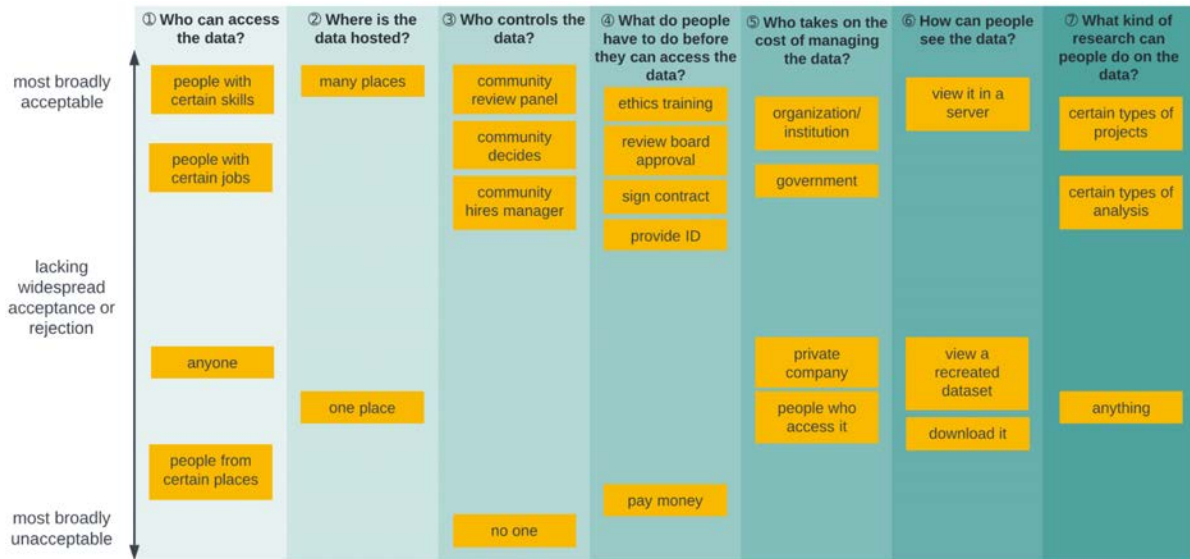
Figure 8.g.3: South Africa Site Deliberative Outputs
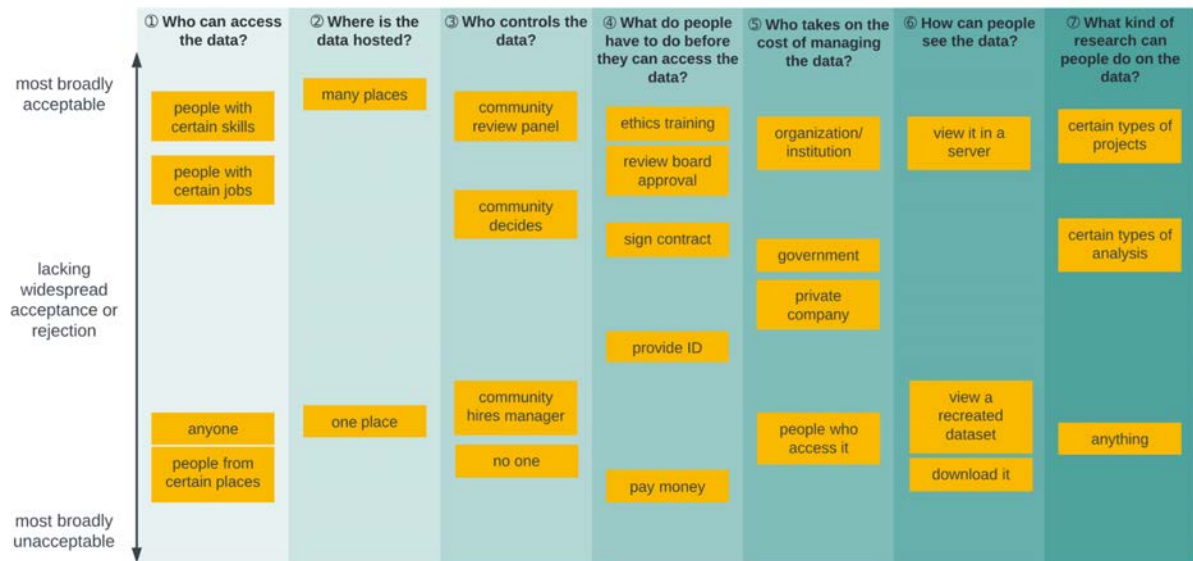
Figure 8.g.4: UK Site Deliberative Outputs

Below is a narrative summary corresponding to these aggregate outcomes and a list of common arguments for the options presented in each question. For a full accounting of evidence supporting these arguments from India, South Africa, UK, and multinational sessions, see Appendix I.8.g.1.

1. *Who can access the data?*

There was no universal consensus. To summarise the argumentation below, participants largely thought that while it was socially just for **anyone** to access the data, it would be prudent for **people with certain jobs** or **certain skills** to handle the data to ensure informed use.

- Allowing **anyone** to access the data is a means of ensuring equality.
- **Anyone** is okay as long as it's for a good reason and/or purpose.
- When **people with certain jobs** or **certain skills** handle the data, they know how to use it properly and/or they won't misuse it.
- Just because people have **certain jobs** or **certain skills** doesn't mean they'll do the right thing.
- **People from certain places** is discriminatory.
- **People from certain places** limits the cross-cultural accessibility of research.

2. *Where is the data hosted?*

This question possibly had the closest to broad convergence of support for **many places** over **one place**.

- When data is stored in **many places** it offers us decentralised power and control.
- The data should be held in **many places** but not *that* many.
- The data should be held in **many places**, but everyone should follow GDPR and/or a similar data protection law.
- Data can't be stored in only **one place** because a fire could burn the data centre down.
- Data can't be stored in only **one place** because it could be hacked or lost.
- When data is stored in **one place** it offers us more privacy and control.

![SageBionetworks logo]

- When data is stored in **one place** it offers ease of management/organisation.

3. *Who controls the data?*

There was no universal consensus. Participants broadly did not want **no one** to control the data, but they debated a range of community-based options. Many participants disliked **community hires manager**, or they wanted to combine **community decides**, **community hires manager**, and **community review panel** in some manner.

- **No one** is concerning because you don't know what could be done with the data.
- **Community decides** would be the best way to fairly represent the entire community.
- **Community decides** would be the best ideally, but it would involve too many people, making it chaotic and/or time consuming.
- **Community decides** could result in a vocal minority having an outsized say.
- **Community hires manager** could concentrate power unduly in one person, leading to bias or overwork.
- **Community hires manager** would be too burdensome for one person to manage such a big dataset.
- A **community review panel** would be more representative of the community and/or representative of areas of expertise.
- A **community review panel** may be too bureaucratic.
- We would like a hybrid of **community decides** + **community hires manager** or **community decides** + **community review panel**.

4. *What do people have to do before they can access the data?*

Most participants wanted a combination of these options. **Ethics training** and **review board approval** were fairly widely supported. **Provide ID** and **sign a contact** were more contentious. The option **pay money** was highly debated.

- Requiring researchers to **provide ID** would help us hold people accountable.
- Requiring researchers to **provide ID** could help us correctly identify people.
- Requiring researchers to **provide ID** could be discriminatory.
- A **contract** can be forged/one could deny that one signed it.
- A **contract** could state the purpose for wanting to access the data.
- A **contract** offers accountability for misuse.
- Requiring researchers to **pay money** could be discriminatory.
- Requiring researchers to **pay money** helps sustain the databank.
- Requiring researchers to **pay money** demonstrates buy-in that protects against misuse.
- Requiring researchers to **pay money** could be done on a sliding scale.
- Requiring researchers to **pay money** may instil corruption.
- A **review board** could assist in ascertaining researchers' economic backgrounds for a sliding scale option.
- A **review board** should be utilised for sensitive, contentious, or for-profit projects.
- Some people might just click through/fast forward an **ethics training**.
- Some professionals already have a code of ethics and do not need an **ethics training**.

5. Who takes on the cost of managing the data?

This may be the least broadly agreed upon question. This question may also have the most variability by country. **Organisation/institution** was probably the most commonly supported option, but again, this question was not widely agreed upon.

- [**People who access it**: lines of reasoning mirrored **pay money** above.]
- A **government** is an obvious funder of the databank because the databank serves the welfare of the people.
- A **government** shouldn't fund the databank because that is taxpayers' money—like a backdoor way of making people pay for it.
- The **government** funding the databank would only be used to further their political agenda.
- Having only one **government** pay for the databank would be unfair, as it is global.
- Not all **governments** would be able to afford or prioritise funding the databank.
- If a **private company** funds the databank, they will have an outsized say in what is done with the data.
- Having a **private company** fund the databank is reasonable if the company is making a product that benefits people with mental illness.
- Having a **private company** fund the databank may benefit the company, but it benefits us in that it helps sustain the databank.
- If a **private company** funds the databank, they may use it to make targeted ads.
- If a **private company** funds the databank, they may leak our information.
- A hybrid of several of these (such as **government** + **organisation/institution** + **private company**) is needed to fund the databank.

6. How can people see the data?

View it in a server may be the most popular option. More concerns were surfaced about **download** and **recreated dataset**.

- A **server** is a secure option that lacks the disadvantages of other options.
- A **server** makes it challenging to do statistical analyses.
- A **recreated dataset** may not be granular enough to capture our diversity.
- A **recreated dataset** is needed for its privacy because this is sensitive mental health data.
- A **recreated dataset** may increase participant openness/honesty.
- Data **download** is beneficial to researchers without a strong internet connection.
- Data **download** does not offer control over data sharing after the fact.
- Data that is **downloaded** is easy to manipulate.
- There should be data that you can **download** and make it self-destruct.
- A hybrid of these, such as **server** view or a **recreated dataset** if researchers desire download, is needed.

7. What kind of research can people do on the data?

Anything was not widely supported. Most participants wanted **certain types of analysis** or **certain types of projects**.

- Maybe **anything** is okay as long as we have exerted control over the other six questions.
- **Anything** is good because we never know what types of research possibilities may be out there.

- Data that is used for **certain types of analysis** or **certain types of projects** would prevent use in marketing or advertising.
- Data that is used for **certain types of analysis** or **certain types of projects** would prevent misuse.
- Data should only be used for **certain types of projects** or **certain types of analysis**, such as mental health or broader health research.

Analytical Outputs

Each of the prominent tensions we observed (Figure 8.f.2) is populated by a few themes, as seen in Figures 8.g.5-8.g.8. Below are descriptions of each theme, exemplary quotes exhibiting these themes, and quotes from each data collection site represented in Tables 8.g.1-8.g.4. Some are unique and some overlap with the in-text quotations.

Control the Data & Access

Figure 8.g.5: Control the Data and Access Theme

Table 8.g.1: Control the Data & Access Quotes

	Control the data & access			
	Skilled access	**Unequal access**	**Who pays / Who is getting paid**	**Where does the data live**
India	"I am constantly thinking about the example that owl model had. Feel that, when we give access to everyone, somewhere, what the results of these kinds of researches will be, will also be accessible by everyone, and then how people, you know, take this information and what they do with it, and how they present it later, will then be to their discretion. And when the general public sees that information, they'll believe it, irrespective of whether that person has the skills to even, you know, work on that data in the first place or not. And that becomes very important, because let's say if I, as a youth, I'm submitting my mental health data from talking about my sleep patterns, who I socialize with how active I am, and I want someone to, you know, take that data and make meaning out of it, I would want that person to have certain skills to at least comprehend and you know, make meaning of it. And not just anyone, because again, those results will bring out a change. And I feel if anyone and everyone can access that data, then that result also will probably bring out a negative shape."	"So I just feel that that you know when it comes to skills, like in general, a lot of skills are accessible to certain communities and certain groups of people because of their socio economic background like not everybody may be well versed with English and hence they might be cut off from you know, certain positions. So I feel like that can be a little complicated in that sense, and gatekeeping in the sense that mental health data"	"in a private company, when it comes to accessing the data, it should be governed by some regulations imposed by the government, or it should be in collaboration with the government. And that would ensure that yes, the, the data's, what is inside it is protected. And that could provide an accountability and that that can work out. Without that without any safeguards attached, without any regulations or something, I would think private company is not acceptable. More of what to say they cannot be allowed to access the data. And organizations or institutions that can be nonprofit one, say, one and the same thing, in collaboration with the government or through any regulation. So that works out. And for government, any regulation, which sort of provides them with with accountability as to where people who have given given their identity, reveal their identity, can challenge or can question their usage and also stuff."	"I feel like we need a sort of decentralisation for this one. To avoid a certain company or or a website or a server, monopolising the whole thing. So, yeah, I guess it can be hosted by several servers. And we can index your engineer's side so that that it will be kept track of as well. And having multiple servers will make it easier than a single server. Like in blockchain when there's a single blockchain, there's always crowding. But when there are parallel chains, it's easier to manage. So I guess Yeah. It should be decentralised."
South Africa	"I'd say acceptable, because I feel like people with certain skills can put it to good use, let's say for example, we are dealing with data, like collecting data from the suicidal group; and we are working with mental health. I think people with certain skills maybe like psychologists and therapists can also, you know, take the data and just have access to it to see the statistics and how they can work around everything. So I go with acceptable"	"I think if the information is hosted in one place then it would set up a boundary between its researchers worldwide because if it's hosted in one place then it's going to be limiting to the outside world besides - let's say it's hosted in South Africa, then it would be limiting to researchers outside of South Africa; some would be able to access it and some would not be able. So I think many places would do"	"Okay, so with this one, I'm unsure of my answer but I would say the people who access the information should pay for it because the information is delicate and it's not just like, just simple details about something not important. It's information about people like, how can I put it? I'm not sure of a way on how to put it; but I would say they should pay for it because the information is important; and its information that is only accessed by them. So they should pay for the cost of managing the information. And for the private company. I was gonna say it's their responsibility, because we as the people that provide the information, we entrust the company with the information, so they are the ones who are supposed to manage it, I think, of course."	"Storing it in one place will enable researchers to know where to find information..but it is going to be a disadvantage when that information is not accessible"
UK	"I agree with this arrangement, also. For the people with certain jobs and people with certain skills, sometimes it may all follow up and sometimes it might not, so maybe data-analysis-wise, maybe you need some data scientists which may not be very good at psychological stuff. So maybe psychiatrists maybe need to work with data scientists to interpret data. So I think that one is more acceptable. Anyone, I also think it's a maybe. Opening data to anyone is good, but we have to think about the education level and the skills of the people who is accessing the data. So it won't be – the data won't get leaked or they can interpret it properly."	"I just feel like it should be fair. Because currently online, there's a lot of research that you can access, but you have to pay for it, so I feel like having just one accurate, global research that's for free and accessible to anyone, I feel like that would be a good start to making more research free. And there could be other ways to fund … Obviously, the people who do the research, they would like to get paid, obviously, but we can discover other ways to make sure that they are paid instead of having to charge people for the information."	"I think I like the idea of all of them, except from pay money. Even though like pay money could cover costs of storing the data and stuff like that, and just paying researchers and things like that, it could be – like, I don't know if classist is the right word to say, but like it makes it so that people with money are able to access the data and people that don't have as much money can't access the data. Or if they're funded by a research company or something like that, or they're solo, like solo researchers won't be able to access the data, but groups can."	"I would definitely say not somewhere where the government has a major influence. For example, I know in China that there are laws, basically, requiring companies to hand over data to the government if the government asked for it for reasons of national security, but that can be quite broad. Also, I wouldn't want it anywhere with data protection requirements that are either not … So, within the EU and the UK, obviously, we have GDPR, so I wouldn't want it to be somewhere that doesn't have GDPR or legislation that has the same level of equivalent protection."
Multinational	"I just think um, the way that sort of, it might be quite naive to say, but the way I've been brought up and the way I kind of see/view society is that some jobs are – do seem to have more trustworthy uh, policies associated with them, if you kinda understand my meaning. Obviously, you know, the role that you do does not – will not um, does not automatically decide whether you're trustworthy or not trustworthy. But just in my mind, some roles would seem more yeah, trustworthy and more likely to handle my data correctly and professionally."	"Uh, over here, you're limiting the people who access it if you make them pay for it. It's getting it because we are not uh, we are comparing a country – we are a developing economy. And your – the people who – who go to colleges, who go to the universities and continue it up to their end are ones who come from well-to-do families or come from privilege. Not everyone can access education."	"I feel that we should take money from those who are very rich or who have lots of money. This will benefit the app. It will also deter misuse. And for those coming from humble backgrounds, we don't ask them to pay money but instead the other options like provide ID. So it will be beneficial for the app, to sustain and maintain it and will also help us make the app more accessible to those coming from lower economic backgrounds." *Translated to English*	"Because you never know what people could do with your data. And it's just a lot more comforting knowing that it's used in your country, rather than globally. But I feel like it really just depends on the data and like, what it's used for. If it's in relation to something that's global, it's understandable but I feel like with mental health, there's also certain factors um, that certain countries may have influence over."

Skilled access: access by people with the appropriate qualifications, appropriate background, appropriate intent, or appropriate purpose. One's background can appear to be appropriate given their degree (like a PhD), occupation (like a researcher), or stakeholder status (like a young person with mental health issues). This does not mean these data users are guaranteed to be harmless—skilled access does not guarantee good impact—it means access ostensibly for the right reasons. This theme includes discussion of one's purpose or the *why* of data access. This theme captures a broadly articulated desire for the *right* people to have access to the prospective mental health data.

> *The least important, huh, Okay, where the data is hosted. So whether it's hosted in one place or many places, as long as the right people have access to the data and can make a difference, it doesn't really matter*
> South Africa Session 3

> *For Anyone, I think, I choose maybe, because it will depend on who is in, because they have to be valid reasons toward the person wants to access the data. and then if the person provides the reasons that are valid then they be allowed to access the*

data, not just anyone, anytime, because some people may want to use it for their own reasons; so I think maybe because they need justification.
South Africa Session 7

Unequal access: how access "rules" affect different groups differently based on cultural group, socioeconomic status, world region, etc. Discussions about equality, the desirability of quality, or what can be done to prevent unequal access also go under this category. This theme included concerns about inequality as well as more dispassionate appreciation of its reality:

All options are right. But this is okay with a large company or when it comes to a private company. But if they are ordinary people of our society, then what will they do? We can't assume that all of them will have the money to pay for the data, right. Big companies and all these will have the funds normally, but how do we take money from who are poor? Can I suggest that there should be difference in the process between the two. That is, say is it possible to that we ask the poor to provide ID only and ask the private companies to pay money and so on.
India Session 2, translated to English

I get what she's trying to say, but I would say, you know, life isn't fair, and you will have to work someday. It's not – I mean, it is – it is unfair, and it is sad, but that's how the world works, and that's something we cannot avoid. So, I mean, yeah, but if – I would be more, you know, open to options if we could just figure out that, how could we not put pressure on individuals?
Multinational Session 1

Who pays/who is getting paid?: value judgments about who pays for accessing, maintaining, staffing the databank, and who (if anyone) gets paid for accessing, contributing to the databank. This theme is not in a 1-to-1 relationship with the question *Who takes on the cost of managing the data?* It is for value judgments and meaning judgments related to the exchange of money in research. This includes discussion about both short and long-term payment, including the long-term sustainability of the databank. This is a highly generative theme that involves who *should* pay, wrapped in the assumptions of the motivations of various prospective funders.

But uh, from the discussion that we had in our country, it was more or less about uh, keeping it to who's ever benefits form the data the most. So uh, they should be managing the cost. So, it can be government, if they are benefiting the most from the data. Uh, if people who are accessing it, they're benefitting the most, then they should be paying for it. And if it's a private company, then they should be paying for it. Uh, but it was also about if the private company takes over the cost, then it'll be uh, too much monopoly on who has like, if they are managing the cost, then it would be like, too much in their hands. The control would be too much in their hands. But if government is paying, then they can always uh, you know, pass out tenders, ask more investors to take over the cost.
Multinational Session 3

I would say the people who access the information should pay for it because the information is delicate and it's not just like, just simple details about something not important. It's information about people like, how can I put it? I'm not sure of a way on how to put it; but I would say they should pay for it because the information is important; and it's information that is only accessed by them. So they should pay for the cost of managing the information. And for the private company. I was gonna say it's their responsibility, because we as the people that provide the information, we entrust the company with the information, so they are the ones who are supposed to manage it, I think, of course.
South Africa Session 8

Where does the data live?: value judgments related to the physical or geographic location of the data. Similar to the previous theme, this is not in a 1-to-1 relationship with *Where is the data hosted?* It is for value judgments and meaning judgments related to the physical and geographic location of the data.

I think it could be bad if all certain countries did it, because some countries are individualistic and some are collectivist. So, let's say if China did it and all places like China, and nobody from the UK had access, it would make, "Oh, how come the UK doesn't? Why are all the other countries?" Yeah, and it might make people worry, say, "Oh, why doesn't somebody from my own country have access to my data? Why is it China? Why is it France?" and you're like, "Is it safe?" or something.
UK Session 2

Because for me, I feel like if my data is shared with someone in the UK, because I stay here, I'd be more comfortable with it because it would be of relevance to the country because I'm living here. But I wouldn't be too comfortable with my data being shared in other places, because I'd want to know the relevance, I'd want to know, who is it being shared with, why do they need the data?
Multinational Session 3

Figure 8.g.6: Can't Control the Data Access and Resignation Theme

Table 8.g.2: Can't Control the Data Access and Resignation Quotes

	Can't control the data access & resignation → relates to a **nefarious undercurrent** in behavior	
	Historic untrustworthiness of researchers & systems	Corruption / bad actors are everywhere
India	"The data can be used for a wide range of purposes. Especially [...] for purpose that aren't already... I mean, that are essentially ethical or aren't essentially for the benefit of these users, but are for other, like political purposes. So yeah, I think...I don't think such purposes should be served by this data. And I feel that the aspect of funding will play a role in that. That's how we have seen things play out."	"I think it's just the general consensus that most private companies in general misuse the data and if this is something sensitive, it's not, I'm not comfortable...having a private company hold on the data. It's bad enough that the Googles and the Flipkart and the Facebooks and the Amazons have our data, I am not going to further exacerbate by providing my other private situation as well."
South Africa	"Okay, I think like, because what I've noticed with some companies when they collect all the data, they normally sell the data to third parties. So I'm not sure if selling people's data is advisable being away"	"How will they know? Let's say maybe the job thing, right? And because there's a lot of corruption and everything, something's reached certain hands, and you never know who gave out the information"
UK	"Yeah, I definitely that, in theory, medical practitioners should inherently have had that ethics training built in, but I don't think that always happens in practice. There has been, you know, what is just blatantly unethical research done by full professionals with PhD. Andrew Wakefield is an obvious example. So I feel like those professionals should still have to be screened for ethics in some way, or trained, just because I don't … Maybe this is just my outlook as a disabled person, but I don't feel like medical professionals can be inherently trusted just because that's their field, basically."	"Some people might not be trustworthy; they might download it and send it to some other people that's untrustworthy, and they might manipulate the statistics and make it seem worse than it is so they could get more money themselfs. Because anybody can manipulate a statistic, so if they can download it, they just might manipulate the statistics to get more money."
Multinational	"I would like to hear other peoples' opinions on that too because I feel like it's very important for somebody to know, like for it to be verified, what the use of the data will be. But then it's also like, um – review boards in the past, for example, can have been um – either biased or they could be discriminative to the certain person with a certain background trying to do a certain thing."	"I think I don't like the idea of a private company, because I just think, um, with, like, capitalism and everything, private companies always seem like they have an agenda, but they have the most money. So, it takes away more of the cost from the researchers and from the institution. Like, would we be able to trust a private company to hold that much data about mental health?"

Historic untrustworthiness of researchers & systems*: Historical or past practices of harm that have degraded the trustworthiness of researchers, institutions, and systems. May involve participants talking about things they haven't personally experienced but rather are aware of and that taint the experience of research for them. This is a highly generative theme that reveals a great deal about participants' positionalities in relation to research institutions.

> *Um, I generally think um, it's unacceptable for anyone to accept or access the data rather. Um, due to how we've seen that people sometimes manipulate data to use it for their own um, unsolicited or unscrupulous um, you know, research. So, I think that it should be uh, limited to specific people, especially if I'm to uh, use the data um, to participate in something pertaining mental health. Um, and there is certain uh, I'm using it for that specific aspect. And I also want people of certain skills uh, to use that data. So, I feel that when anyone can use it um, it could somehow lose a lot of um, value in that. So for example, I think uh, for the longest times, I think it was in the '70s that it was deemed that black people um, before that black people were seen as*

people who couldn't get um, depression. And also, I think about 30 years ago it was uh, seen that uh, being gay or being homosexual is a mental illness. So, I think that certain things are due to all, how we've seen how history has played out. Um, being accessible to anyone um, does to an extent make one feel vulnerable to um, you know, people using that data for wrong, unjustifiable um, reasons. So, that's why I feel like, perhaps it shouldn't be accessible to anyone but should be accessible to people of certain jobs. Not to say that people of certain jobs and certain skills uh, will not have a racist bias or homophobic bias, etcetera.
Multinational Session 5

Yeah, I definitely that, in theory, medical practitioners should inherently have had that ethics training built in, but I don't think that always happens in practice. There has been, you know, what is just blatantly unethical research done by full professionals with PhD. Andrew Wakefield is an obvious example. So I feel like those professionals should still have to be screened for ethics in some way, or trained, just because I don't … Maybe this is just my outlook as a disabled person, but I don't feel like medical professionals can be inherently trusted just because that's their field, basically.
Participant 2, UK Session 1

A note on language use: We have opted to shift from a trust/mistrust paradigm that is located in participants' choices to a trustworthiness/untrustworthiness paradigm that places the onus on institutions to be worthy of the trust of marginalised people. For more information on how research institutions can shift the focus to becoming worthy of trust, see Warren et al., 2020[47].

Corruption/bad actors are everywhere: primarily relates to the presence of current system actors that can be bribed or corrupted. Juxtaposes with **skilled access** above in that these actors have impure motivations, inappropriate qualifications, or inappropriate background.

SAP48: *Because with Board approval, we might find out that the person that's trying to access the information has connection with some of the board members.*
Moderator4: *So you think maybe it might kind of be an avenue for people to kind of get in because of their connections rather than because of their merits?*
SAP48: *Yeah, I feel like they wouldn't get the information because they qualified to but because they know someone*
South Africa Session 8

Some people might not be trustworthy; they might download it and send it to some other people that's untrustworthy, and they might manipulate the statistics and make it seem worse than it is so they could get more money themselfs [sic]. Because anybody can manipulate a statistic, so if they can download it, they just might manipulate the statistics to get more money.
UK Session 2

Figure 8.g.7: Benefits of Data Sharing Theme

Table 8.g.3: Benefits of Data Sharing Quotes

	Benefits of data sharing	
	Normalise / destigmatise / start conversations around mental health	Protect / understand mental health
India	"But I think for everyone, if somebody is curious, or if somebody is, say a content writer who has to write a certain article on mental health, then for them I think the research done on the data provided would be enough to, to justify their means or to satisfy their curiosity."	"Yeah. So, I feel that though, I accepted that certain types of analysis and projects could be done regarding the data, but then again, I feel that mental health should be the centre of all those things, just as we just as we discussed regarding the vitamins deficiency, so there would be another reason for example, we are focusing on a particular age group facing depression because of unemployment. And so that analysis, that kind of analysis should also be allowed, but certain types of projects which are being carried out. So if we focus on all the affecting factors which are causing mental health issues, then it might be chaotic. So keep them for the purpose of keeping it focused on more on or would be more targeted. I think certain types of projects should be restricted towards mental health only while certain types of analysis should be open for the factors which are affecting mental health."
South Africa	"I think from my side, why I think the community deciding should be unacceptable is because a community can be easily influenced into anything so for example right now with the current pandemic that we are in, there exists a community of anti vaxxers and should that community decide you know, I felt I feel like my my safety would be threatened in a way so I feel like the community should not be deciding rather experts and people who are more clued up about the data should be the one to decide because they are the ones who usually come up with the research and that thesis, you know"	"It should be acceptable so that we can be able to gather information from each country and continent as a whole. So that way the World Health Organization can be able to get data from each country, and then they can be able to put it into good use; and also that because if someone from, let's say, UK, gets information from people in South Africa, they're able to, like, help us in a certain way in things that we don't know. So it's always good for people in certain places to know information"
UK	"I think people with certain skills, it depends what skills. If the skills are, for example, an app developer, for example, if an app developer ... Obviously, to develop an app, you need certain skills, and if they are trying to develop an app that's aimed towards helping with mental health or just educating people about mental health, then I think, yeah, they should be able to use the data so that it's accurate and it includes everyone, because it's global data from different countries, all countries. "	"I think it would actually be really good if the government could access it, because it would enable them to plan more kind of like efficient mental health services. I feel like no one could – in the UK especially, where we have socialised health care, I think it's really beneficial for the government to be able to see data like this and access it, which I guess is more of an argument for them paying for it, because no one will benefit from it more."
Multinational	"There's still a lot of stigma around mental illness. Especially in – our – okay, I – I will speak for where I am. Most people think it's witchcraft or it's just something that is weird. They don't have that mentality that it could be mental illness or something serious that can be mental – that needs professional help. So, I think it – it would be safer to – for like, professionals in specific to have such information in order – in order for them to modify, change things. And for the public as well, for their personal growth and to know how to seek help when they – they actually need help."	"Like, if there's um, an increase in depression for example in a certain country, I feel like that data collected would be relevant to that country specifically, because there may be factors in that country influencing that. If that makes sense."

Normalise/destigmatise/start conversations around mental health: relates to the global mental health databank as a means of destigmatizing, normalising, or stimulating conversation between people about mental health. This theme is primarily about the benefits of research to community members.

I guess seeing patterns on how people develop mental health issues so we can work on how they stop people developing them or how to improve mental health when people have bad mental health. Just things that would make life better for people with mental health. Even stuff like teaching people to behave around people who've got mental health issues; any kind of help like that.
UK Session 3

SageBionetworks

There's still a lot of stigma around mental illness. Especially in – our – okay, I – I will speak for where I am. Most people think it's witchcraft or it's just something that is weird. They don't have that mentality that it could be mental illness or something serious that can be mental – that needs professional help. So, I think it – it would be safer to – for like, professionals in specific to have such information in order – in order for them to modify, change things. And for the public as well, for their personal growth and to know how to seek help when they – they actually need help.
Multinational Session 3

Protect/understand mental health: relates to the global mental health databank as a means of better understanding, diagnosing, and treating mental health issues. This theme is primarily about the benefits of research to researchers.

The most attention should be paid to who can access the data; because I feel that mental health is such an important issue, which is usually underrated, especially in our country. And it shouldn't - this survey or the data shouldn't fall on deaf ears or people who cannot do anything about it. It should actually go to experts who can make a difference and save people
South Africa Session 3

Yeah. So, I feel that though, I accepted that certain types of analysis and projects could be done regarding the data, but then again, I feel that mental health should be the centre of all those things, just as we just as we discussed regarding the vitamins deficiency, so there would be another reason for example, we are focusing on a particular age group facing depression because of unemployment. And so that analysis, that kind of analysis should also be allowed, but certain types of projects which are being carried out. So if we focus on all the affecting factors which are causing mental health issues, then it might be chaotic. So keep them for the purpose of keeping it focused on more on or would be more targeted. I think certain types of projects should be restricted towards mental health only while certain types of analysis should be open for the factors which are affecting mental health.
India Session 5

Figure 8.g.8: Risks of Data Sharing Theme

Table 8.g.4: Risks of Data Sharing Quotes

	Risks of data sharing		
	Leaky data / lost data	Spectrum of sensitive vs. non-sensitive data	Fear of losing and/or disbelief in anonymity
India	"So this is what, and also answering the question about what is the worst thing that could happen if the data gets leaked, if the data is just out there for anybody to see, talking from a lived experience perspective, I think if the data is just out there, for any person who might be putting their information on the databank, it could be very triggering, and very, you know, they could be a little anxious about that a little. Not so willing to do it, because they would know that, okay, this data is just going to be out there. It's not, you know, I do not have any control over who can access this data. So I think that is what I feel in that is why I wouldn't want that data to be public."	"Yes, in a way, that's what I'm saying. We can also look at it, just like safety protocols in a way. Just for the more sensitive information, there should be a more more stricter safety protocol for the data to be shared. So a graded, graded sharing arrangement in which the information which can stay anonymous, should stay anonymous and should be available to everybody. But information which with the consent of the people, and which is sensitive, should be shaed with the consent of the people, with those people who need it through agreement as was proposed in the model. Octoplus model."	"One misuse I can think of is that, if the private company gets access to people's IDs, etc., if they get information from it, then using internet or social media they can reach people through advertising. For example, when we login to any app, then you get more advertisements of that app. Like get that app, login to that app, there are so many offers. So private companies do this."
South Africa	"I think as I've said earlier, with regards to recreational data is possibly accurate with download. I feel that should people be able to download it then it kind of hinders how the data is actually controlled and then makes access kind of not problematic as busy but uncontrollable. If that makes sense. I knew how to create some form of boundaries around downloaded items. You can throw like a standard item. So it's viewed and as you can kind of manage everything through this server"	"I like the part where you said it doesn't like reveal any sensitive parts; because that's the reason why I didn't say anything about the recreated dataset, because I didn't understand that part. I thought maybe it shows like every detail, the name, the age, the location of the person and all that. So now that you've explained it, I feel like it's good, because it doesn't reveal any sensitive information about a person. So it's good"	"It's important to me because of, before you can even access access that data, you need to know. Like, things have protocols. So already there are conditions in terms of the contract. Already, there's a person who's supposed to control it. Before you can even view it, there are certain stages that must happen before the end of result. So all of this applies. And I feel like that is the last stage because of if I sent the contract, and I felt like no, I wanted my things to be private. And then I see it, like maybe on internet and everybody can access it. Everybody can see it. It simply means now, my contract was been breached, somehow. So I feel like it's very important because of it's the last part of it was the last decision maybe the organization made, which, like, must also comply to my contract. So you cannot, I cannot view it on internet if I did not sign for that."
UK	"Yeah, same for me. I would put both of them in 'maybe' because it depends how encrypt they are and how safe it is and how are you going to store it, I feel like. Because, yeah, just as anyone say, if it's in many places and it's well-encrypt, then it doesn't matter because it won't just leak, but if it's just one place and then it leak and all the data's gone, then all the work is gone."	"Yeah, so I think some data should be available to everyone, but some characteristics, stuff like race and age, some categories where someone could possibly discriminate should be protected because it's very easy … Like it's been easy to see during the pandemic, a lot of people are – when data's open to the public, people can misinterpret it and then spread it around and come to a conclusion, say that the data supports it when, in reality, they're missing something or they haven't done it properly. So I think in that case, there should be some parts of data where it could be sensitive that only certain people should have access to – people with ethics training and people who now how to actually handle data properly."	"I guess I wouldn't necessarily want to restrict it, but I think depending on the area you'd want to take into account how identifiable that data could become to someone in a certain region. Like if you were specifying someone was from a small Welsh town, and the people from the small Welsh town can access it. Like as long as that's been taken into account, then I wouldn't have issues."
Multinational	"The reason why I chose many places was because the data can always get like, um, I don't know, like can get broken down or can get deleted or something like that. And I just think that it's better to be safe than sorry. Like, one place is too much liabilities, but many places, it's more safe."	"I think all three can be used as well. So, with the viewing in a recreated data set, that could be a possibility for people who need it. If somebody approaches the initiative that they want to access mental health data, then they could be asked the question, do you require raw data or could you use the recreated data set? And um – depending on their views and depending on their needs, they could get which type of version they need."	"That would be – because then that kind of introduces the question like um, obviously everyone's got little bits of that data. Are they gonna be able to – how much in that data that they've got, can they use to identify people."

Leaky/lost data: the fear or concern of participants that data can be lost, leaked, or manipulated. This was effectively an *in vivo* code as participants used the word "leak" verbatim.

> *Even if there is a password in the computer, we also have hackers who hack through computers, so information is easily leaked.*
> South Africa Session 3

> *And also, with one place, if something ever happens to that one place – like, it's happened in the past, like overheating can fry the cords, or if somebody intentionally, like an arsonist goes and burns the place for example. I don't know why they would do that, but that could happen. Or a crash or something. If it's just in one place then that jeopardizes all of the hard work, all of the data collected.*
> Multinational Session 7

Spectrum of sensitive vs. non-sensitive data: articulations of sensitivity and what constitutes sensitive data.

> *Like, if it's some sort of data with more implications, more sensitive kind of data, then it should be. It could be placed behind a paywall, but things for the general information of the public or even more specific kind of information, that should be made accessible for them. It shouldn't always be kept behind a paywall for the general public.*
> India Session 6

> *So if we are giving access to the data to everybody, so what we can do is, we can compartmentalize the data in terms of its sensitivity. And we can compartmentalize, just as you gave the example of the Polish government Protego Safe app, or Protego, Safe application, or whatever it was. So that application can be used as a way in which to compartmentalize the data in a way as to have datasets which are anonymous, and which not be, which did not necessarily be named the people need not be necessarily named. So data can be compartmentalized in that way. Like the demographic information except for the name, everything else, if the people agree to, the responders agree to, those things can be kept anonymous, and they can be shared with everybody. But if it comes down to the personal histories, so they can be shared with the consent of the people with the selected set of people. So that amount of specialization if the databank is willing to have so that could also work in a way.*
> India Session 1

Fear of losing and/or disbelief in anonymity: the fear that anonymous data is not truly anonymous, or the idea that even if it is anonymous, it is still too personal to be shared. This theme is distinguished from the participant misunderstanding articulated in Section 8.g "Misunderstandings" in that this theme captures participants with a thorough understanding of research anonymization that have a fear of re-identification or anonymization procedures that are not sufficiently stringent.

> *One misuse I can think of is that, if the private company gets access to people's IDs, etc., if they get information from it, then using internet or social media they can reach people through advertising. For example, when we login to any app, then you get more advertisements of that app. Like get that app, login to that app, there are so many offers. So private companies do this.*
> India Session 2, translated to English

> *I guess I wouldn't necessarily want to restrict it, but I think depending on the area you'd want to take into account how identifiable that data could become to someone in a certain region. Like if you were specifying someone was from a small Welsh town, and the people from the small Welsh town can access it.*
> UK Session 4

Methodological Findings

Despite following the same procedure in Section 8.f that enabled themes to emerge from the multinational transcript data, we did not identify major thematic constructs that were not captured in the original framework (Figure 8.f.1). As such, we coded the multinational data

using the same set of themes, and multinational data is used above as exemplar quotes. There are, however, some differences between the Round 2 (multinational) and Round 1 (in-country) data that we attribute to methodological effects:

1. At the multinational level, we noticed participants demonstrating more awareness of how different countries may interact with a given governance policy.

    ○ Participants with greater frequency than at the Round 1 sessions imagined how data governance choices would affect people outside their own country:

    > *With the contract, um, different countries have different um, systems, different governments.* [...] *a contract made in the UK perhaps wouldn't have the same value, let's say in a different country around the world. And different countries have different laws. So perhaps signing a contract here might be like hold value but not the same value in a different country.*
    > Multinational Session 5

    > *Um, I think the paying money, it makes sense that institutions subsidize the payments and stuff, but where my mind goes is, like, in the UK, like, you'll have unis that can afford to subsidize more for their students than other unis. And if it's a global, like, globally, people can access the data, then it's sort of like, how many institutions would be able to subsidize that payment, and also, if there's individual people that wanna access the data, they have to pay a lot more, um, compared to researchers, um, that are part of a uni, um, or an institution.*
    > Multinational Session 1

2. We also noticed participants telling less personal stories and relating data governance choices less to their own lives than they had in Round 1 sessions.
3. Facilitators also sometimes noted participants changing their position between in-country and multinational sessions.
4. Occasionally we saw them participate in the mechanics of the procedure like trying to strike up compromises or directing questions to each other.

These observations may have clear methodological reasons. Observation (1) is perhaps just the natural result of having participants of multiple nationalities in the (virtual) room. For some participants, it may have even been the first time they had met an individual from India, South Africa, or the UK. With the national distribution of participants at top of mind, participants may have been more thoughtful about how data governance affects people differently.

Observation (3) may be attributable to the composition of participants in Round 1 versus Round 2 sessions. There were a handful of instances where participants in a Round 1 session, despite our efforts otherwise, were acquainted with each other in some way. In one session in the UK, for instance, two participants who joined the Zoom meeting appeared to be in the same room based on audio feedback and their comments in the chat box. In another instance, the South African PYA noted that the participant who shared a thoughtful

reflection on medicalized racism and homophobia (quoted in full above under **Historic untrustworthiness of researchers and systems**) in a Round 2 (multinational) session had taken a rather different perspective in the prior Round 1 (in-country) session. One possible reason for this shift, as articulated by the PYA who had had a debriefing conversation with the participant, may be that the participant had acquaintances in the Round 1 session who may pass judgement on such a statement. In the Round 2 session, conversely, participants were perfect strangers (facilitators were instructed not to invite participants from a shared Round 1 session to a shared Round 2 session), and it may be more challenging for participants to find a shared connection or search someone on social media across vast country borders.

Observation (4) may be attributable to the fact that Round 2 utilised the same protocol as Round 1. Because participants knew we were engaged in a consensus-building process, knew we would ask them to group options into *acceptable*, *maybe*, and *unacceptable*, and knew we would seek compromises between participants, it is perhaps unsurprising that they would begin to take up these actions themselves.

These phenomena, while interesting, may merely be a function of familiarity with the process (i.e. holding two rounds of structured deliberative sessions using the same protocol, one with same-country participants and one with multinational participation.) This may also be a function of context as the qualitative discipline assumes that data shared are contextually constructed in real time, meaning participants may say different things or have different opinions depending upon their context[48].

Misunderstandings

We also saw two persistent misunderstandings from participants. Distinct from the theme **fear of losing and/or disbelief of anonymity** (Section 8.g "Analytical Outputs"), which reflects a sophisticated understanding of how, in the era of big data, datasets can be combined to become re-identifiable, we additionally observed a fundamental misunderstanding of anonymization. Some participants' statements indicated that they believed a future databank would still contain identifiable information such as names, addresses, phone numbers, email addresses, date of birth, or national ID number, even though we had specified that data contained in it would be anonymized. We called this the **lack of anonymity misunderstanding**. It is of note because if participants do indeed believe that this identifiable information is part of a databank, it may meaningfully influence their decisions for governing such a databank.

We saw this misunderstanding in the questions that participants asked:

> *Will the data be kept anonymous? So, say, if we do datas from … You said it's going to be global, so if you can sort it by country to country, say, if we do, for example, Italy, if we do data from there, will the names and if an address is needed, will all that be kept anonymous?*
> UK Session 1

As well as the contingencies that they acknowledged:

> *Um, if the data is being, uh, p – uh, people can see the data, uh, be it either downloaded or view it in a server, um, I think it depends whether our names are included or not. If our names are…included, I think that would obviously make it more uncomfortable…But, uh, while in a recreated dataset since, uh, I think even the names are changed.*
> Multinational Session 8

> *So for instance, if it is anonymous, then I feel like anyone should have access to the research*
> India Session 6

And the value statements they put forward:

> *Um, I think that people's identities shouldn't be revealed because it takes away the privacy*
> South Africa Session 6

Or the level of researcher access that they envisioned:

> *You could just search someone's name and date of birth and it would come up*
> Multinational Session 9

As evidenced by these quotes, participants exhibited a lack of clarity about what identifiable data (or lack thereof) is left in a dataset, and their preferences were dependent on the identifiability (or lack thereof) of such data. This is distinguished from the theme **spectrum of sensitive vs. non-sensitive data** (Section 8.g "Analytical Outputs"). This theme captures how data regarding some *topics* (e.g. mental health, sexual health, illegal activity) is more sensitive than other *topics* (e.g. favorite color). The **lack of anonymity misunderstanding** evinces the belief that information that is systematically removed from datasets would somehow potentially be accessible to people who were not involved in its collection.

The **lack of anonymity misunderstanding** was not ubiquitous among participants, but it was common enough to warrant the recommendation that future participant education must be more thorough in detailing how data is anonymous. While the educational materials did contain statements to this effect, it is evident that a much more in-depth review of what is or is not included in a de-identified dataset is needed.

A second misunderstanding present in the data was **therapeutic misconception**[49]**.** This misconception was infrequently identified but is sufficiently well-described in the literature that it bears discussion. When participants described how they envisioned a global mental health databank, occasionally it appeared they were unaware that the primary intent of a research databank is to facilitate research (i.e., producing generalizable knowledge), not the provision of individual-specific clinical care.

Participants at times envisioned a mental health app as a mobile psychiatric device rather than a data collection tool:

What if like, sharing deep things helps me out like, getting out communicating my problems to the App helps me out. And like, those things are not known. Like, maybe I'm the only person who knows. And the App helps me like to communicate with it. And I trusted it with my data.
South Africa Session 6

The App that is being created is a little like a kind of clinic, where people are able to search for answers to their questions or search for solutions. It feels like a kind of clinic. When we are sick, we go to a doctor and he charges us fees for the consult
Multinational Session 2, translated to English

Or they appeared to imagine that participants would interact directly with psychologists:

Psychologists and therapists or counsellors or scientists, I feel like they should be allowed to use the data 100%, because they're the ones who can help people, make sure they get the help they need.
UK Session 1

For example, how will tribals, NT DNT [Nomadic and Denotified Tribes] *communities be able to reach out to a psychologist for help who have not even had access to schools/education.*
Multinational Session 2, translated to English

As IndiaP20 said, giving money - in fact people will not give money. They will think that why should I give my money to tell them my problems. So they will not voice their problems. Everyone has problems, how will they pay money? Then they will not think about their problems and not come forward to tell about it.
India Session 2

While participants did broadly understand that a mental health databank produces generalizable knowledge (Indeed, the theme **protect/understand mental health** (Section 8.g "Analytical Outputs") is a nod to the value of research), participants did occasionally focus on specific clinical applications of a mental health databank. Again, this is an area where it is incumbent upon the research team to set appropriate expectations with participants.

Quality Assessment

In light of the intervention from De Vries et al., 2010[50], into the field of deliberative democracy that attempts to map some standards for assessing quality of deliberation, we adapted these methods for our own quality analysis. We used an exit survey as well as our own qualitative data to analyse four metrics of quality: (1) equal participation, (2) respect for the opinions of others, (3) adoption of a societal perspective, and (4) reasoned justification of ideas.

The exit survey does have several limitations. First, each exit survey entry does not represent a unique individual. Following Round 2 (multinational) sessions, wherein all participants were sourced from earlier Round 1 (in-country) sessions, participants were routed to the same online survey. Accordingly, there are more responses from participants

marking their home country as UK (n=52) than there are unique UK participants (n=45). UK participants are also better represented in this exit survey dataset than Indian and South African participants (n=40 and n=38, respectively).

Correspondingly, despite our efforts to distinguish the in-country (Round 1) responses from the multinational (Round 2) responses by asking participants to select *Multinational* as their country, many participants in multinational sessions still selected their home country, making it difficult to disentangle first round unique participant responses from second round repeat participant responses. As such, respondents marking their country as Multinational (n=29) does not reflect the number of multinational participants (n=61), nor the number of multinational participants who took the survey but marked their country as India, South Africa, or UK. For the complete de-identified exit survey results, see Appendix I.8.g.2.

1. Equal participation

While De Vries et al., 2010[50], measured the volume of text contributed by each participant, the multimodal ways in which participants contributed to our study make this a challenging metric to replicate. Coupled with participants who joined late, left early, or experienced technical difficulties, we did not feel that volume of text was a meaningful measurement in our case. Instead, we are reporting our facilitator training strategy for ensuring equal participation. Facilitators were instructed to solicit the opinions of participants who were quieter and to seek approximately equal participation of the three countries in Round 2 (multinational) sessions. Facilitators directly solicited participants with statements like "I would be interested to hear [name]'s thoughts on this" or "Does anyone from South Africa have an opinion to share?" Another effective strategy was assigning a number to each participant and making a request like "Let's hear from the even numbers" when conversation became stilted. Despite our best efforts, it was challenging to obtain true equal participation in this context. For more information, see Section 8.e "Learnings."

2. Respect for the opinions of others

Our metric for this item is adapted directly from De Vries et al., 2010, which asked "Do you feel your opinions were respected by your group?" (on a scale ranging from 1 = "not at all" to 10 = "very much"). The average of De Vries and colleagues was 9.4 (SD = 1.0). Ours was similar: 9.6 (standard dev=1, median=10, range (1,10) (n=150) (Figure 8.g.9). We again replicated De Vries and colleagues' next question on the same scale: "Do you feel that the process that led to your group's responses was fair?" Again our results were similar: De Vries found a mean of 9.7 (SD = 0.7). We found a mean of 9.5 (standard dev=1, median=10, range (5,10) (n=143) (Figure 8.g.10).
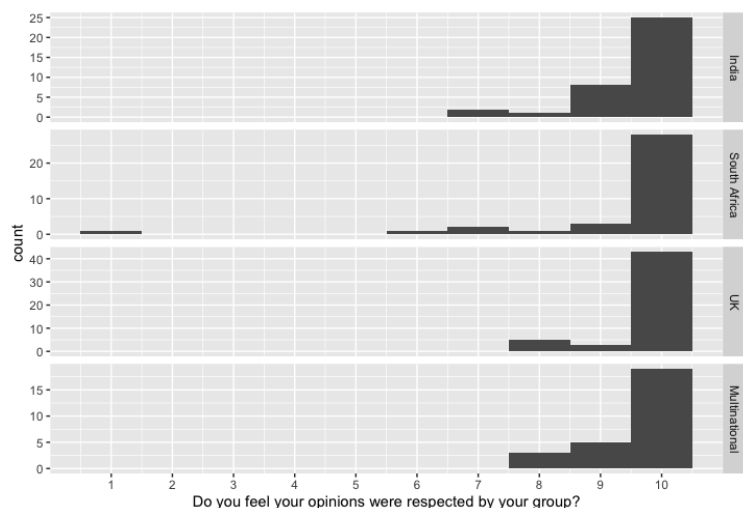
Figure 8.g.9: Do you feel your opinions were respected by your group?
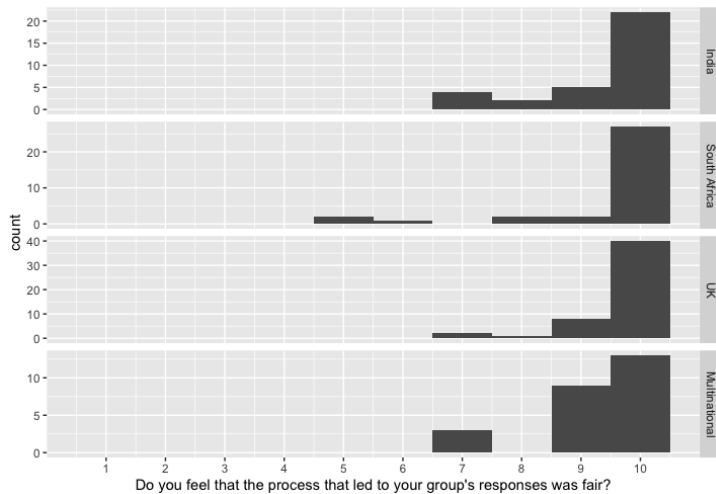
Figure 8.g.10: Do you feel that the process that led to your group's responses was fair?

3. Adoption of a societal perspective

We adapted the inquiries of De Vries et al., 2010, for this metric. De Vries inquired at different time points whether participants would allow a surrogate to decide to enrol them in a gene transfer study (54% affirmative immediately following the study) and whether participants would use surrogate consent to enrol a loved one in a gene transfer study (41% affirmative immediately following the study). We asked two adapted questions at a single time point immediately following the study: (1) If a global mental health databank was created according to the specifications your group chose today, would you contribute data about yourself? (2) If a global mental health databank was created according to the specifications your group chose today, would you recommend that your community contribute data about themselves? The response to (1) was 91% percent yes and (2) was 93% yes.

Notably, our "yes" rate is considerably higher than De Vries, which is perhaps attributable to the relative clinical invasiveness of a gene transfer study as compared to an informational databank study.

4. Reasoned justification of ideas

As reflected in Section 8.g "Deliberative Outputs", participants shared richly reasoned arguments for why certain options may or may not be desirable. Sessions were not without "Because I said so" justifications—as defined by De Vries et al., 2010—but facilitators were trained to ask follow-up questions, as exhibited by this exchange:

> SAP48: [in response to the question *Who controls the data?*] *Okay. So I would say* no one *is acceptable.*
> Moderator4: ***Could you elaborate on why?***
> SAP48: *I say* no one *is acceptable because if you meet the requirements in whatever process you have to undergo, then it means you simply qualified or like you, yeah, it means you qualified; and the information should only be given or not given, like, it should be accessible to people with the necessary qualifications to access the information.*

There are methodological reasons why a participant may not initially share a fully reasoned response, such as the limited time for discussion, the awareness of consensus building as a goal, or the hesitancy to "take up too much space" with their comment. Participants may also have faced challenges articulating their thoughts in their second—or third or fourth—language but were broadly willing to work through their preferences when prompted. Additionally, as exhibited by the open text responses below wherein participants reflect on

the value of hearing from others, that participants warmly received the discussion aspect of the session suggests the richness of the interpersonal communication displayed.

Our exit survey also contained an open response question ("Please use this space to share any additional thoughts."). A brief content analysis of open text responses follows.

Respondents shared broadly complimentary comments on the research process:

"Very well facilitated discussion"

"The session was very informative"

"I really liked this session and it was a great experience."

Some shared recommendations to improve the participant experience of data collection:

"Make a document that the group can communally edit (ie google slides)"

"There were certain areas that were unclear, such as what all would be considered under the mental health database, how and where the data would be stored, etc."

"I loved the idea of poll [sic]*. I think it would have been amazing to have another poll at the end regarding all 7 questions, that way probably we would have been able to figure out the right options. I think next time when we are done discussing the best options for the questions, share a poll."* [In this particular session, the facilitator had cut the final poll for time.]

Whereas some appeared to finish comments from the discussion itself:

"I also think it is important that a person who's [sic] *information is being managed can be asked what they prefer and choose for themselves who should handle this data."*

"i think a mental health databank would be very valuable but there would have to be many stages of ethics before it could be created. everyone who contributes their data must be highly informed regarding the nature of the data being stored, how it is stored etc"

"Data about mental health and mental health related studies should be accessible to students and s researchers [sic] *just for the purpose of understanding the community better, providing them better help and doing better by the people."*

"Sharing data about yourself really helps not only the researchers but also the whole community as well as the global community to stay informed about different aspects by looking at the trend in that statistics [sic]*."*

"I think the Global Mental Health Databank needs to think about how to make this data truly accessible to everyone-- marginalised communities, people from lower economic backgrounds, people speaking different languages"

Many reflected on the value of the discussion experience itself:

> *"This was an insightful session and it really educated me at a level which I needed and I would be happy to join future sessions if possible."*

> *"During our discussion people made me be aware of lot of things"*

> *"I felt really heard and that everyone had the opportunity to speak and share their thoughts. I feel like it is so important for people to be involved in these conversations. The call was really interesting too and the hosts ensured the atmosphere was welcoming."*

> *"as an individual coming from a country that is vastly different from those within the meeting, there were many commonalities that we were able to decide on during the session. some topics did require more of a discussion and debate, while others were collectively decided."*

As reflected in the quotes above, among those participants who shared an open text response, their comments reflect engagement, willingness to continue the conversation, and some unintentional (yet welcomed!) benefits of the study to those who participated.

h. Limitations

A number of limitations to the qualitative study have been previously articulated, especially related to the challenges of remote data collection (see Section 8.e "Learnings"), the incomprehensibility of some terminology (see Section 8.b "Learnings"), and the sensitivity of participants to procedural and methodological choices (see Section 8.g "Methodological Findings"). Further observations on limitations that have not yet been discussed are below.

Despite admirable standardisation among facilitators, a few stylistic differences between facilitators may have influenced participants, especially in light of participants' attention to detail. For instance, in regard to the option *no one* under the question *Who controls the data?*, one facilitator explained what it would look like to have *no one* controlling the data as "a big button that says 'get data'" that researchers can press within the web portal, whereas other facilitators presented *no one* as algorithmically controlled data. Neither of these explanations is inaccurate, and both are possible. Indeed, "a big button that says 'get data'" could merely be the UI representation of an algorithmically controlled data management system. However, facilitators elicited specific types of responses when they used the word *algorithm*:

> *Um, I was just gonna say, like with the AI* [artificial intelligence] *and stuff, um, like it's – I think it's known that, like, Google and, um, just a lot of algorithms in general can be – have their own biases, just based on, like, previous things that they've learnt, because humans are gonna have biases, and they learn that kind of stuff. So, I think the idea of AI* [artificial intelligence] *controlling the data, to me, is kind of, um, not scary, but I just think it's risky, knowing that, like, the way our society is, we kind of force our technology to become like us, in the sense that we have biases and, like, things like that.*
> Multinational Session 1

While these discussions were highly generative, their appearance was contingent on a participant or facilitator (more often the latter) using the term *algorithm* or *artificial intelligence*. Resultantly, this influences the consensus building process and the deliberative outcomes therein.

Furthermore, the order of the 7 data governance questions themselves may also influence participants' choices. The organisation of the 7 governance questions is effectively chronological, leading with an a priori question about access (*Who can access the data?*) and concluding with a question about what, once access is obtained, is allowable behaviour with the data (*What kind of research can people do on the data?*). We found that participants naturally considered these questions cumulatively rather than in isolation. Accordingly, one of the most common arguments made (see Section 8.g "Deliberative Outputs") regarding the final question was "Maybe **anything** is okay as long as we have exerted control over the other six questions." It is reasonable to assume, then, that if this question were ordered first, the nature of the argumentation would differ. This is perhaps less of a limitation as it is a note about interpretation of these data; like any qualitative data, responses to individual questions should not be divorced from the context in which the conclusion was made. Participants routinely referenced prior questions and anticipated future questions in their lines of argumentation.

In addition to the ways in which the study population is limited by technology barriers and linguistic medium, we also noted instances where participating in the study was not fully accessible to people with disabilities. While our research teams were particularly cognizant of how participants' mental health may impact their interactions with the data collection process, we neglected to make every component of the study accessible for a range of disabilities. For instance, the educational videos did contain audio and corresponding captions for their entire duration, but there were semiotic representations that were used that were only presented visually. The behaviour of animated characters and the use of imagery were meant to further participants' understanding of the educational content, but these visual representations are not available to participants with limited sight. Furthermore, while each session utilised Otter.ai to produce live captions, these automated captions were frequently inaccurate and were not available to non-English-speaking participants. Regrettably, the bias in automated transcription software[51,52] was particularly evident in Round 2 (multinational) sessions, where the captions underlying the speech of some accent types were more accurate than other accent types, which may have an othering effect on participants in the latter category. Caption inaccuracy is also a shortcoming in accessibility, as participants with limited hearing or auditory processing disorders are disadvantaged by erroneous captions.

Finally, the study team failed to adequately prepare for participants who may bring another person with them to assist in their participation in the session. In one session, a participant who joined with a parent initially caught the study team by surprise, and they came to understand that the parent was helping the disabled participant contribute to the session. This instance demonstrated a failure of the study team to prepare facilitators for participants joining with interpreters, skilled nursing assistants, or other individuals who may assist in their participation. Additionally, training in informed consent for individuals assisting participants would be prudent as well.

Despite these shortcomings in accessibility, the study team benefited immeasurably from participants who identified themselves as disabled and examined data governance through a disability justice lens. We are grateful for these rich contributions.

9. Data dissemination and researcher perspective

Abstract

We engaged members of the DUAG and other external researchers to respond to specific queries and tasks created to assess usability of current standards for data access and databank usability, as well as to gather new requirements. These tasks assessed both procedures for data access as well as databank/portal functionality. For one of these exercises (the card sort exercise), we also compare with youth perspective, since most data portals are typically designed only with researchers in mind. We describe 3 exercises conducted with these groups to determine preferences for access, use, and dissemination of data.

a. Current portal functionality feedback

Approach

In July 2021, UW and Sage team members held four virtual small group sessions with members of the DUAG to review a Synapse database comparable to the MindKind databank (Figure 1) and provide feedback on the usability of the web-based platform. The groups reviewed two data sharing projects: a Parkinson's study project and an asthma study project. These were selected because they contain digitally collected passive and/or survey data. Participants from India, UK, South Africa, Brazil, Nigeria and the US participated. The groups were convened by country or region (1. India, 2. UK, 3. South Africa/Nigeria, 4. US/Brazil), and context-specific issues arose in most discussions.

Figure 9.a.1: Sample Synapse Database Webpage

After an overview of the study progress and an orientation to the session, the following questions guided the discussion.

- How user-friendly is the site?
- How helpful are site instructions for data access?
- What more, if anything, would you like to know about the context of the data collection study participants?
- How useful are the discussion functions?

- What kind of research community would you like to access through the site (e.g., for collaboration, for technical support, for study design, or other)?
- What are the limitations of this site for data use?

Sessions lasted approximately 50 minutes and were recorded.

<u>**Learnings**</u>

DUAG members provided feedback in six areas.

Background/Study Materials

- Researchers recommended that the web-based platform display more information about the study materials. In the context of MindKind, this could include copies of consent forms, copies of tools and assessments, as well as clear explanations of active ingredients. A DUAG member noted, "If you come in with no knowledge of the data, it would be useful to have a breakdown of the demographics, to see what kinds of information the dataset is providing, to see the depth of the data."

Data Analysis

- Researchers were interested in seeing a clear process for vetting research and proposing analyses, general support for use of the data with information on where to get help if needed, and options for querying the database that would not require knowledge of R or other statistical programs.

Data Presentation and Access

- Researchers inquired about these elements of data access:

  - Level of skill required to access the data;
  - Whether the site could provide examples of what had been done with the data (e.g. how app-based data were processed, other analyses of the data, including links to the code);
  - Whether data be presented in pie charts or other accessible formats (as the NIH data repository does);
  - Whether there would be costs associated with data access; and
  - The best ways to provide simplified overviews of the data.

Factors Affecting Data Quality

- DUAG members reflected on context-specific concerns about data collection and quality

  - Completeness of site level data collected for analysis remains to be seen.
  - Missing data and non-response for long [periods of] time for longitudinal data could affect analysis.
  - How does Synapse address multiple researchers working on the same data analysis and issues with data ownership?
  - Identifying [participants] with access to technology on a regular basis and time to enter data would be a challenge.

- For collection of mental health information, the illness and current severity status can affect the data entry process of the participants.
- Entry of data such as suicidal ideation might require prompts from the site to seek further help by directing participants to nearby services or providing numbers that they can use to access help.

Researcher Community

- Researchers wanted to know if the databank design process considered the "digital divide", i.e., limitations in access to or facility with technology.

  - Would the databank be accessible to the range of stakeholders that youth work with?
  - What skill level would a citizen scientist need to use the information?
  - How could data users best communicate their progress to the research community (e.g., analyses, manuscripts in progress)?
  - They requested more clarity on the use of the discussion function on the Synapse site.

User Experience

- Use images or video to simplify instructions, draw users to the site, and depict procedures (e.g., flow charts)
- An abundance of text might be informative, but can also be off-putting
- First time users of such sites require clear navigation aids

Recommendations

Overall, DUAG members recommended clear, easy to read instructions with minimal dense text to guide user navigation of the Synapse platform. They supported the use of images and video to draw users to the site and to depict study procedures.

Procedures to access the data should not require knowledge of sophisticated statistical packages that might create barriers to a wide range of users.

Given DUAG interest in access to study tools, a catalogue of consent documents and assessment tools should be available on the platform. Information orienting visitors to the study should be comprehensible to researchers and lay people.

b. Requirements for a GMHD

Approach

In November 2021, researchers naïve to the study and youth advisors participated in a card sort exercise presented on a virtual white board (Miro) to explore databank requirements. A 2-step process was presented to participants (Box 9.b.1).

Box. 9.b.1 Card Sort Procedures

Step 1: Brainstorming

For this exercise you will be answering the following brainstorming prompts by typing your answers/ideas into a blank sticky note. There are multiple people contributing to the same board, so you may see stickies already populated by other people. Please do not delete/edit anyone else's contributions, even if you disagree. Feel free to add your own ideas, even if they conflict with others.

Step 2: Ranking Top 3

For this exercise you will be voting on the ideas which you submitted in Step 1. You will have 3 votes for each section/prompt. You will rank your top 3 answers (you can also vote for the stickies others have placed if you desire). To do this exercise, move the numbered circles for each section (these will be colored in the actual exercise so you know which circles to move to which section), to the stickies which you find most important in each section. Please use 1 for the most important, 2 for the second, and 3 for the third most important.

Researchers and youth responded to these 8 open-ended questions:

1. *The biggest challenge in understanding data from other researchers' studies is…*
2. *As a researcher interested in mental health coming to a databank I would like to be able to do the following...*
3. *It's important that I know these things about the data…*
4. *I would like to filter and view available data by…*
5. *For an overview of the data, I would like to see…*
6. *I would like to work with youth as co-researchers by…*
7. *I would like to talk to _____ about _____ ...*
8. *I would like to see the following from others (eg: researchers/youth/databank providers) on a regular basis...*

Learnings

Researchers

Researchers (N=8) provided a total of 145 suggestions in response to the open-ended questions. We identified 31 primary and 24 secondary themes that are grouped in association with each open-ended question. See Appendix I.9.b.1 for detailed results.

1. *The biggest challenge in understanding data from other researchers' studies is…*

    Primary Themes
    - Insufficient environmental and situational context during data collection
    - Understanding how data is coded
    - Data collection methods not fully described
    - Assessing data quality (ex. representational sampling)

    Secondary Themes
    - Finding and accessing data

- Balancing sufficient context with confidentiality
- Insufficient variables / keys

2. *As a researcher interested in mental health coming to a databank I would like to be able to do the following...*

   Primary Themes

   - Compare data across populations over time (cross-national, longitudinal)
   - Explore relationships and patterns in data
   - Identify risks and protective factors (individual/family/social/policy)
   - Benchmark findings against their own data

   Secondary Themes

   - Study social determinant effects on mental health
   - Prevalence of MNS disorders in underrepresented populations
   - Mine personal narratives from data
   - Understand mental health stigma in different communities

3. *It's important that I know these things about the data…*

   Primary Themes

   - Context of data collection and methods used
   - Sampling strategy, process and tools
   - Data collection method and storing methods (security/safety)

   Secondary Themes

   - Ethical data collection standards and IRB approvals

4. *I would like to filter and view available data by…*

   Primary Themes

   - Country
   - Age
   - Gender
   - Basic sociodemographics
   - Time/Date

   Secondary Themes

   - Level of peer support received
   - Family structure/dynamic
   - Education
   - Income

5. *For an overview of the data, I would like to see…*

   Primary Themes

   - Quality of life by country
   - Mental, neurological, and substance use disorder prevalence by country

- Mental, neurological, and substance use disorder data by sociodemographics
- Visual / graph overviews

Secondary Themes

- Description of key covariates and outcomes
- Study abstract

6. *I would like to work with youth as co-researchers by…*

Primary Themes

- Conceptualise data collection approaches
- To identify gaps in study design
- Community based participatory research
- Identify their needs, concerns, and important outcomes, and incorporate them into study

Secondary Themes

- *Assist with data analysis*
- *Getting their help with recruitment and dissemination*

7. *I would like to talk to _____ about _____ …*

Primary Themes

- Youth about what to look for in data
- Youth about how to interpret the data
- Youth about how to present the data

Secondary Themes

- Youth + Researchers about developing interventions
- Family / caregivers about their fears
- Experts about data interpretation
- Youth about resilience

8. *I would like to see the following from others (eg: researchers/youth/databank providers) on a regular basis...*

Primary Themes

- Key emerging insights
- Innovations around participatory research
- Study impact and innovations
- Papers from study research

Secondary Themes

- Challenges with the dataset collected (and solutions for those challenges)
- Understand how youth is being impacted / influenced by ongoing research involvement
- Wide dissemination across platforms
- Educational content (videos)

These are insights derived from top rated themes by researchers:

1. A primary concern is about data quality and understanding how it was gathered.
2. It is important to establish if data collected is relevant / has attributes that they need for further exploration
3. There is strong interest to partner with youth throughout the study lifecycle.
4. There is interest in using this study to advance co-research methods and understanding
5. From the Sage perspective, there are no surprising aspects of what researchers would expect as it falls in line with similar projects.

Youth

A sample of youth advisors also took part in a similar card sort activity to answer the following 8 questions:

1. *What I most want to learn about youth mental health from the databank is…*
2. *As a young researcher or citizen scientist coming to the databank, I would like to…*
3. *I would like to work with researchers by…*
4. *I would like to talk to ____ about ___*
5. *I would like to see the following from others (eg: researchers/youth/databank providers) on a regular basis…*
6. *It's important that I know these things about the data…*
7. *I would like to filter and view available data by…*
8. *For an overview of data, I would like to see…*

Youth participants produced 37 primary themes and 27 secondary themes.

These are preliminary insights derived from top rated themes:

1. Youth want to be involved, listened to, and have direct means of participation.
2. The specifics of involvement are not as important as that they are involved, both with scientists and with each other.
3. Communication of progress and findings (or lack of) is key in addressing involvement and trust.
4. Justice and equity are significant concerns, especially when it comes to uses of data and policy outcomes.
5. Youth expressed particular sensitivity with how data is secured, eventually used, and that it is not misused for profit or exploits participants in any way.
6. Interfaces for youth will likely have to be specific to their needs (i.e different from researchers).
7. Youth take a global perspective, caring about other locations / age / genders / ethnicities, not just their own.

Recommendations

These are preliminary recommendations based on researcher and youth feedback about what to consider when designing the functionality of MindKind product (portals, apps etc.):
- Metadata about data collection context is always available
- Metadata about all data collection methods and specifics is available

- Share data quality assessments by individual scientists with the whole researcher community, to inspire confidence in quality
- Interface tools that allow for comparative scenarios
- Periodic summary of progress delivered to all interested subscribers
- Ability to choose which aspects of the study to receive news about
- Ability to see latest analysis
- Option for co-researchers / youth to review analysis and publication (even if unofficially)
- Explicit, readily available, outline of all ethical considerations taken in the study
- A place specifically for youth groups, where they can discuss the study and latest results
- How and why certain participant attributes are tracked should be easily available on data portal.
- The Synapse data portals feature set is highly applicable and has most of the functionality needed already

c. Acceptability of data access procedures

Approach

We recruited researchers on the DUAG and in the wider community to evaluate the steps for accessing data on the Synapse platform. These researchers joined an individual session with a Sage team member to walk through the 6 steps required to access MindKind data and to provide feedback.

1. Register for a Synapse account
2. Become a Certified User
3. Become a Validated User
4. Request Access to the MindKind Pilot Data
5. Accept the terms and conditions of data use when prompted
6. Access the data

See Appendix I.9.b.1 for detailed illustration of each step.

We posed three evaluation questions:

1. Do participants understand concepts related to data access and governance?
   - These concepts include: Access restrictions, access requests, intended data use statements, IRB approval, access reviews, and data use.
2. Can participants complete the key Data Access tasks in the system?
   - Identifying their current level of access to the study data.
   - Reading and acknowledging the Terms & Conditions of Data Use.
   - Requesting access to the MindKind Pilot Data.
   - Competing workflow steps, like including upload an IRB letter and populating an Intended Data Use Statement.
   - Downloading the data to the devices.
3. Do participants understand the purpose of the Certification and Validation requirements? How can the existing data governance processes above be clarified or improved?

Individual sessions were run with five participants. Four of the participants were DUAG members, and one was not. All participants had experience making access requests as a researcher. All five participants were asked to create an account on the Synapse platform prior to the exercise. Four participants created an account, and one did not: for this participant, a pre-registered account using a Sage-owned email address was utilised. Access to this account was removed following completion of the session. Other than creating an account, none of the participants reported having used the Synapse platform before the exercise.

These three tasks were completed by all participants
1. Request access to Controlled Plus Tier Data
2. Provide feedback on the Certified User Quiz
3. Provide feedback on Validation

Learnings

Table 9.c.1 shows learnings from each task.

Table 9.c.1: Data Access Evaluation Tasks and Learnings

Task	Summary & Selected Quotes	Key Learnings
Task 1: *Request access to Controlled Plus Tier Data*	Participants were asked to navigate to a controlled dataset, request access to it, fulfil the access requirements, and then download the data after the request was approved. This was a think-aloud exercise: participants were given a task to complete, and asked to verbalise their thinking while doing so.	All five participants were able to complete the task. Lack of Help Text or Confusing Text were the most commonly reported source of confusion, followed by Perceived affordance Issues (see the following slides) Users repeatedly suggested that an example Intended Data Use Statement, available at the time they were asked to provide their own, would have been helpful. Several participants suggested improvements to the Add Requestors component, including more flexible suggestions, and clearer labelling. Several participants suggested ways to improve orientation for first time users.
Task 2: *Provide feedback on the Certified User Quiz*	Participants were shown the certification quiz, and asked to provide feedback about it. Due to time constraints, they were not asked to complete the quiz. "It's like a step in the right direction, but I'm not convinced that the person who, who scores high on this quiz is the one who knows best or will enact … an appropriate use of the data" (Session 1)	All participants understood the purpose of the Certified User Quiz. All participants understood the value, but several participants stipulated that they would only find it valuable when the data it restricted access to was sufficiently valuable to warrant the time commitment to complete it. Two participants suggested that the format of the quiz could be improved by splitting it into several steps, rather than asking all questions at once.
Task 3: *Provide feedback on Validation*	The moderator described the identity validation process, and the participants asked questions, provided feedback, and made suggestions. The participant was not asked to complete identity validation as part of the exercise, due to time constraints. "I would, I would expect such a step to occur... We all know we live in a very difficult environment… fake identities, things getting hacked…. you can't protect against that entirely. But on the other hand, you can make it clear to people who're contributing data that you are... taking reasonable steps to ensure that legitimate people are doing legitimate stuff." (Session 2)	All participants saw value in the task. When asked to compare, most participants saw more value in Validation than in Certification. Validation was considered necessary: "I would hope that you do that..." The most common concern raised by participants was whether the amount of effort required for the validation process was warranted by the data. Another, related potential concern was the lag time between requesting validation and being approved for it. Participants suggested surfacing relevant information about the dataset to help them decide whether validation was worth their time.

<u>Recommendations</u>

Overall, researchers were satisfied with the process of data access, but their main questions related to a) greater clarity in instructions at specified steps and b) indication of dataset content so that users could determine its relevance to their needs. Recommendations for each task are as follows (See Table 9.c.1 for detailed context).

Task 1: Clarify the affordance of UI elements in the data request process through simple instructions or visual aids, so that users understand the capabilities of each element in the process.

Review and revise existing language in the text for UI labels, given differences in interpretation among participants.

Add additional "help" text on specific pages to orient new users (e.g. Entity page and Intended Data Use Statement and Data Requesters sections).

Task 2: Consider editing the format of the Certified User Quiz by dividing it into several steps rather than posing all questions at once.

Task 3: Given time requirements for the identity validation process, consider providing a brief description of the dataset so that users can decide whether the dataset is of interest to them.

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Section II - Evaluation of project outputs relative to pre-determined success criteria (Go/No Go Criteria)

Area 1. Ethics and governance

Area	Go	Not sure	Stop
Ethical and Governance "How do we make sure the model for data control is sustainable, responsible and fair?"	Clear governance structure in place for both data being banked and data being accessed using FAIR criteria (findable, accessible, interoperable, reusable) a) Written down b) High acceptability to data contributors across all geographies- 50% say that they are clear and happy with the principles laid out. c) High accessibility for researchers who are not part of the team - >60% say that they are clear and happy with process.	Clear governance structure in place for both data being banked and data being accessed using FAIR criteria a. Written down b. Acceptabile to data contributors across all geographies- 25-50% say that they are clear and happy with the principles laid out. c. Accessibility for researchers who are not part of the team - 25-60% who seek access say that they are clear and happy with processes	Clear governance structure in place for both data being banked and data being accessed using FAIR criteria a. Not written down. b. Not acceptable to data contributors - less than 25% say that they are clear and happy with the principles laid out. c. Not accessible to researchers who are not part of the team - less than 25% who seek access say that they are clear and happy with processes

Topline: Go with one caveat: in India, less than 50% of (42.3%) youth who entered the consent workflow enrolled in the study across all governance models (40.8%-44.1%). However, of the participants in the qualitative study, 87.5% of Indian youth said they would want to participate in an eventual global mental health databank.

It is important to note that, as we have highlighted elsewhere in this report, privacy and data protection regulations and the privacy concerns and preferences of the public generally and young people specifically are in a period of active evolution around the world at this time. While we were able to establish a clear data governance system for this project, designers of a future GMHD will need to do so flexibly, with an eye to preserving data usability to maximise the scientific benefit of the data resource.

Detail:

    a. Yes, we have clearly written procedures for accessing the data.

> A mock project with the data controls that would be applied to the quantitative data was hosted on Sage Bionetworks' platform for data sharing and analysis, Synapse (link to the mock project: https://www.synapse.org/#!Synapse:syn26230633/wiki/613292). The data management components of this platform have been used to support data sharing for dozens of large-scale multi-institutional research consortia and >40 remote digital studies capturing the lived experience of people. Synapse provides a collaborative workspace that enables worldwide sharing of scientific resources and data, with robust governance procedures for data use restrictions and ethical oversight. Over the last 7 years, Synapse has facilitated the work of >33,000 researchers from >150 countries who have shared >17 million files. It has also supported management of longitudinal data collected directly from over 230,000 individuals in digital health studies including data collected through questionnaires, passive monitoring, structured and unstructured written responses, images, and linkage to external databanks including for wearable integration.

> We asked nine naive researchers to attempt to access the mock project. Seven of nine found the written instructions for access to the mock project clear.

    b. >50%* of data contributors found the data governance structure acceptable

> In the quantitative study arm, more than 50% of UK (60.6%) and South African (56.8%) youth who entered the consent workflow enrolled in the study. However, less than 50% of Indian (42.3%) youth who entered the consent workflow enrolled in the study across all governance models (40.8%-44.1%). One team member suggested that these relatively lower consent rates may be a reflection of language as a barrier to the informed consent process in India.

> A limitation of these data is that the data governance model did not significantly impact the likelihood of enrolling in the study overall (nor did age or gender); country and lived experience did impact likelihood of enrolling, with youth with lived experience more likely to enrol regardless of data governance model.

> In the qualitative study arm's exit survey, more than 80% of youth from each of the three countries said they would contribute their data to such a databank (87.5%, 89.5%, 92.3%, and 93.1% from the India, South Africa, UK and Multinational sessions, respectively.) In contrast to the participants in the quantitative study, these participants received in-depth education about the governance models presented.

    c. >60% of naive researchers attempting access are clear and happy with the access process

Nine researchers attempted the access procedures for the mock project in Synapse. Greater than 60% (8 of 9 researchers) said they would be willing to go through this process to access future data from a global mental health databank. However, three of nine were somewhat unsatisfied with the process; their comments are below (Table II.1.1).

A similar interview-based study found high acceptability (Table 9.c.1).

Table II.1.1: DUAG Data Access Protocol Feedback

Positive feedback	"It will only over time that the process, and its pluses and minuses, will become clearer."
	"I have previously used Synapse to access data and the process used here is generally smooth and well-explained throughout. Steps for accessing and manipulating data (i.e., what occurs after these steps) may be less clear without additional instruction as well."
Negative feedback	"It looked pretty similar on screenshots but when I tried to perform certain cases like validating the profile, it was somewhat confusing to follow the instructions and locate relevant documents."
	"The system only works up to validating your profile. After that you are unable to request access - there is no button as indicated in the screenshot so the system stops short here."
	"Sign up was really straightforward and simple. However, it was not clear how to validate my account. You must go into account settings which is not described in the instructions (says to go to profile homepage). I was unable to follow the remaining steps due to time"
	"There are so many hoops to jump through. I would personally NOT complete all these steps, knowing that I can likely find equivalent data elsewhere. If the data in question has been collected using public money then I find the various steps more like obstacles than reasonable limitations, and I don't think they are in the spirit of the current imperative to make all data public, where reasonable"

Area 2. Data specification and structure

Area	Go	Not sure	Stop
Data specification structure and Analysis "How should the data be specified and structured to make sure useful studies can be done?"	Set of core data items agreed that relate to relevant potential research questions How these data are structures in database is specified Data specified and structured to support analytical requirements for the following question or subsets of it "what works for whom and why"	Data items too poorly specified to be clearly captured Data items unrealistic and cannot be captured Specification of database overly complicated Analytic plan not realistic	Data items cannot be specified or captured, No specification for database No analytic plan

Topline: Go. While future efforts may be made to refine the study protocol and/or add additional areas of study (i.e., AIs), data collection and specification was demonstrated to be feasible and data sharing and analytical requirements collected from the DUAG were largely addressable for the study data.

Detail:

Data specification and structure was not a primary focus of our overall project. Prior to this feasibility study, Wellcome had described a menu of Active Ingredients for mental health on which they wished for us to focus our data collection efforts. Further, Sage Bionetworks has extensive experience in structuring datasets to enable open research which it leveraged for this project.

Data collection (Active)

The data collection process for the MindKind Study app was developed in collaboration with the PYA and YPAGs. We presented three different scenarios to the YPAGs and incorporated their feedback into the design of the survey. We selected the survey cadence that was deemed the least burdensome by YPAG members. The YPAGs also informed strategies to maximise engagement with surveys, such as reflection exercises and GIFs for performing surveys.

Active data collection focused on survey completion. We timed the length of each survey type and found that on average daily surveys took no more than 5 minutes to complete, with a range of 30 secs to 5 minutes, with the weekly survey taking an average of 9 minutes, with a range of 3 to 22 minutes. Though, final week feedback suggests that future work can be done to lessen the burden of participation.

SageBionetworks

The numbers of surveys completed per participant enrolled in the quantitative study were median (IRQ) = 5 (4, 8), 6 (4, 14), and 8 (5, 16) for India, South Africa and the UK, respectively, and the proportion of participants contributing at least 50% of the 88 protocol surveys was 3.8%, 5.3% and 10.1% in India, South Africa and the UK, respectively.

Youth in arm 1 of the quantitative study were able to select their active ingredients. We found that youth selected Sleep and Social Activity most often.

Table 6.e.5: Active Ingredient selection (Arm 1), count (percent)

| Characteristic | N | Arm 1, N = 793 | | |
		India, N = 140[1]	South Africa, N = 136[1]	UK, N = 517[1]
First AI	793			
BodyMovement		8 (5.7%)	11 (8.1%)	40 (7.7%)
PositiveExperiences		22 (16%)	17 (12%)	50 (9.7%)
Sleep		49 (35%)	34 (25%)	194 (38%)
Social		61 (44%)	74 (54%)	233 (45%)

[1] n (%)

Notably, we did not see that being able to choose active ingredients translated into longer engagement; youth who had active ingredients selected for them (arm 2) remained engaged longer than those who were able to select their active ingredient (arm 1). Our primary hypothesis was that participants given a choice of study topic would show more engagement than those without a choice. While we observe a significant difference in retention by engagement arm, we actually find that Arm 2 (pre-assigned AI model) were retained longer in the study than those in Arm 1 (self-selected AI model) (log-rank test for survival p-value = 6.3e-4).

Data collection (Passive)

Participants in the MindKind Study app could opt-in to passive data collection. Passive data collection included ambient light, battery statistics, charging time, data usage, and screen time.

Table 6.e.7: Participants providing passive data as a proportion of those completed the "About You" baseline survey (or consenting to the study).

	India	South Africa	UK
Ambient Light	21.6% (10.0)	14.6% (6.0)	24.1% (17.7)
Battery Statistics	28.6% (13.2)	26.1% (10.8)	39.3% (29.0)
Charging Time	25.8% (11.9)	23.0% (9.5)	36.8% (27.1)
Data Usage	28.2% (13.0)	23.5% (9.8)	34.9% (25.7)
Screen Time	29.6% (13.6)	24.6% (10.2)	42.0% (31.0)

Data loss may be an important component of feasibility for the future GMHD. To try to quantify data loss, we compared participants' stored AI with the AI inferred from study completion + stored AI. In India, South Africa and the UK, respectively, we observe 1.6%, 14% and 8% missingness of AI annotation. While this is almost certainly an underestimate of data loss, it does give us some insight into data expected vs. data observed. It is important to note that due to the much lower engagement in India, the bias (underestimation) is likely greater in that jurisdiction. For larger files, data loss may be larger. For example, the relative ratio of Ambient Light passive files (> 50 MB) to Battery Statistics passive files (typically < 1 MB) 0.69, 0.47 and 0.61 for India, South Africa and the UK, respectively, suggesting that more than 50% data loss may be occurring for the largest files in South Africa, and closer to 40% or 30% for the UK and India, respectively.

Data Structure

Data can be structured in long table format according to data science best practices to allow query and extraction of data according to research questions. Given the longitudinal nature of the data metadata about time/date in the study must accompany survey data (e.g. below). Accompanying data dictionaries will detail the full questions and possible answers.

Table II.2.1: Example data format

healthCode	survey	question	daySince Baseline	date	answer_string	answer_numeric
BAQhseUFQ xB-wiGnqdrL OXom	BodyMovementDaily	Mood_Daily	1	2021-08-03T19:23:51.570+01:00	Average	3
BAQhseUFQ xB-wiGnqdrL OXom	BodyMovementDaily	3M_Daily_Locale	1	2021-08-03T19:23:51.570+01:00	Hard	1

Researcher feedback and requirements

DUAG members suggested these requirements for usability of GMHD data relating to the way the study protocol is described and linked to study data:

1. When multiple data entries are associated with specific variables, specify the time point at which the data entries are available (e.g. baseline, 1st follow-up, 2nd follow-up, etc.)
2. Create clear connections between the methods and the data structure, e.g. links between the wiki that describe methods information and the data itself.

These can easily be addressed by thoughtful design of a study website including thorough description of the data collected, the study protocol (i.e. which data were collected on what cadence) and navigation links between the data descriptions and associated data (e.g. easy navigation between the description of the sleep data description and the sleep data).

They also suggested ways in which the data should be structured in order to facilitate analyses of interest:

3. Ensure maximal coverage of as many biopsychosocial variables as possible in varied formats: time series, longitudinal, as well as high dimensional data.

4. Structure the data presented such that there are clear linkages between passive sensing data and self report data from study participants.

Storage in well formed data structures such as those recommended above facilitate the automated transformation between formats as recommended in (3). Additionally, the inclusion of timing data (e.g., dayInStudy above) facilitates the temporal linkage between different data types (i.e., survey and passive data).

In some cases, researchers requested information which was not feasible/acceptable from a participant privacy and ethics board perspective:

5. Enable access to geospatial data tied to youth home locations or neighbourhoods. Researchers would need access to multilevel data combining individual-level exposures and outcomes with neighbourhood-level exposures that are inferred from individual-level GPS and gathered from routine geospatial data sources.

This highlights that in some cases, information requested by external researchers does not align with the privacy-preserving practices expressly desired by youth and required by ethics boards.

Area 3. Participant engagement

Area	Go	Not sure	Stop
Engagement data contributors "How do we collect high quality mental health data?"	Engagement meets industry benchmark (1%) i.e. of those who start using the databank they contribute at least 50% of their data according to the protocol agreed with them over a 3 month period such that have data on at least 100 people in at least two geographies	At least 1% of those who start using the databank they contribute at least 50% of their data according to the protocol agreed with them over a 3 month period such at have data on at least 100 people in at least one geography	Cannot gain 1% engagement (or less than 100 people) in any geography

Topline: **Not sure.** Engagement surpassed the industry benchmark: greater than 1% of participants contributed at least 50% of their data over 3 months in each country. This translated into more than 100 participants in the UK, however, this was fewer than 100 participants (n = 18 and 20) in India and South Africa.

Detail:

The proportion of participants contributing at least 50% of the 88 protocol surveys was 3.8% (n=18), 5.3% (n=20) and 10.1% (n=119) in India, South Africa and the UK, respectively. Lower recruitment in India and South Africa, and greater drop-off in numbers downloading and interacting with the study app (54%, 59% in India and South Africa versus 26% in the UK) contribute to the failure to reach the 100-person benchmark in India and South Africa.

In-app study retention differed significantly by country with median (Interquartile range (IRQ)) = 2 (1,13), 6 (1, 41), 11 (2, 44) days for India, South Africa and UK, respectively (log-rank test for survival p-value < 1e-5) (Figure 6.e.1, Table 6.e.2). In context, a previous meta-analysis of mHealth studies in the US observed a median number of days of retention of 2 for this age group[1]. This is also generally more than that observed in the uncompensated mental health study, Start (median = 2 days), however it is substantially shorter than the mental health study, Brighten, in which participants were compensated for their participation (median = 26 days)[1].

6.e.2: Study retention probabilities for 2, 4, 8 and 12 weeks.

Characteristic	14 Days	28 Days	56 Days	84 Days	p-value[1]
Engagement Arm					<0.001
1	35% (32%, 38%)	26% (23%, 29%)	16% (14%, 18%)	8.8% (7.2%, 11%)	
2	41% (38%, 44%)	31% (29%, 34%)	19% (17%, 22%)	13% (11%, 15%)	
Consent Model					0.9
B: Researcher Norms	38% (34%, 43%)	27% (23%, 31%)	17% (14%, 21%)	10% (7.6%, 13%)	
A: Participant Choice	38% (34%, 43%)	31% (27%, 35%)	19% (16%, 22%)	11% (9.1%, 15%)	
C: Democracy/Download	38% (34%, 42%)	29% (25%, 33%)	17% (14%, 20%)	11% (8.5%, 14%)	
D: Democracy/Server	37% (33%, 42%)	28% (25%, 32%)	17% (14%, 21%)	11% (8.7%, 14%)	
Lived Experience					0.4
FALSE	34% (29%, 41%)	28% (23%, 34%)	16% (12%, 21%)	11% (7.7%, 15%)	
TRUE	38% (36%, 41%)	29% (27%, 31%)	17% (16%, 19%)	11% (9.5%, 12%)	
Gender					<0.001
Woman	37% (34%, 39%)	28% (26%, 30%)	17% (15%, 19%)	10% (9.0%, 12%)	
Man	34% (29%, 40%)	26% (22%, 32%)	15% (11%, 20%)	9.2% (6.4%, 13%)	
Transgender/Nonbinary/Multiple/Other	47% (41%, 53%)	36% (30%, 42%)	24% (19%, 30%)	14% (11%, 20%)	
Prefer not to say	58% (44%, 76%)	42% (29%, 61%)	24% (13%, 42%)	18% (9.4%, 36%)	
Country					<0.001
India	24% (20%, 28%)	16% (13%, 20%)	9.5% (7.2%, 12%)	5.5% (3.8%, 7.9%)	
South Africa	39% (34%, 44%)	32% (28%, 37%)	16% (13%, 20%)	9.0% (6.6%, 12%)	
UK	43% (41%, 46%)	33% (30%, 35%)	21% (19%, 23%)	14% (12%, 16%)	

[1] Log-rank test

Area 4. Sustainability

Area	Go	Not sure	Stop
Sustainability of databank "What business model will create a sustainable databank?"	Clear plan that meets the requirement of the commission but allows financial stability ongoing, or with a clear exit plan Plan should align to principles of open science, FAIR data access, innovation and inclusion as well as product sustainability.	Plan written down but does not meet all requirements	Not possible to come up with plan.

Topline: Stop. While we were able to establish youth preferences regarding fiscal stewardship of their data, these preferences do not readily translate into a self-sustaining business model for a databank. We do not see a way to responsibly commoditize something that the majority of prospective participants are fundamentally opposed to being a commodity without some impact on who joins, who contributes, what they contribute and/or for how long they participate.

Detail:
The fiscal sustainability of a global mental health databank rests upon who hosts the data and if sufficient fees are paid by researchers accessing the data or making discoveries with it to cover in whole or part the cost of hosting. Fiscal stability of large scale data resources is a source of tension around the world. At this time funding for the majority of such databanks comes from governments and multi-institution consortia (many of which rely heavily on public funding).

In the quantitative study arm, select youth in arm A, as well as those in arms C and D could express their preference regarding the use of data for profit and fees for using the data. While a majority of participants from all countries responded that comercial companies should have to pay to use the data, they equally preferred that their data not be used to make a profit (Table 4.i.). Requiring commercial companies to pay for data access and prohibiting their eventual profit making from using the data would likely disincentivize commercial use of the eventual databank.

Table II.4.1.: Quantitative arm youth preference regarding profit and cost

Question	India, N = 628[1]	South Africa, N = 529[1]	UK, N = 1,018[1]
Can my data be used by researchers to make a profit?			
Yes, my data can be used by researchers to make a profit.	187 (30%)	170 (32%)	109 (11%)
No, my data can NOT be used by researchers to make a profit.	353 (56%)	307 (58%)	610 (60%)
I don't care if my data is used by researchers to make a profit..	88 (14%)	52 (9.8%)	298 (29%)
Do people have to pay to use my data?			
Nobody should have to pay to use my data.	216 (34%)	190 (36%)	369 (36%)
Only commercial companies should have to pay to use my data.	365 (58%)	310 (59%)	468 (46%)
I don't care if people have to pay to use my data.	47 (7.5%)	29 (5.5%)	181 (18%)

Within the qualitative study arm, the question of who bears the cost of managing the data and the question of fees for use of the data were addressed as deliberative outcomes. Youth felt strongly that the cost of data collection, storage, and management should be borne by an organisation or institution rather than by a government, private company or, lastly, by those accessing the data (Figure II.4.1). Key arguments focused on issues of equity and justice, as well as on fears of corruption (Table II.4.2).

Figure II.4.1: Qualitative arm youth preference regarding profit and cost
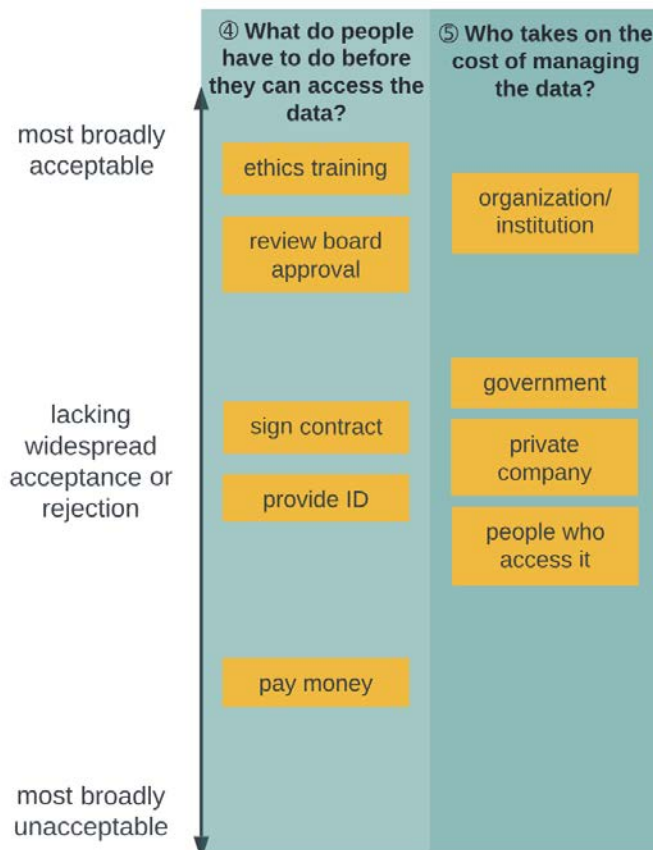
Table II.4.2. Qualitative arm arguments regarding profit and cost

Should there be fees to access the data? Who takes on the cost of managing the data?

- Requiring researchers to **pay money** could be discriminatory.
- Requiring researchers to **pay money** helps sustain the databank.
- Requiring researchers to **pay money** demonstrates buy-in that protects against misuse.
- Requiring researchers to **pay money** could be done on a sliding scale.
- Requiring researchers to **pay money** may instil corruption.

- A **government** is an obvious funder of the databank because the databank serves the welfare of the people.
- A **government** shouldn't fund the databank because that is taxpayers' money—like a backdoor way of making people pay for it.
- The **government** funding the databank would only be used to further their political agenda.
- Having only one **government** pay for the databank would be unfair, as it is global.
- Not all **governments** would be able to afford or prioritise funding the databank.

- If a **private company** funds the databank, they will have an outsized say in what is done with the data.
- Having a **private company** fund the databank is reasonable if the company is making a product that benefits people with mental illness.
- Having a **private company** fund the databank may benefit the company, but it benefits us in that it helps sustain the databank.
- If a **private company** funds the databank, they may use it to make targeted ads.
- If a **private company** funds the databank, they may leak our information.

- A hybrid of several of these (such as **government** + **organisation/institution** + **private company**) is needed to fund the databank.

Section III - Reflections of PYAs on Study Structure, Outcomes, and Recommendations

The PYA were integral to the MindKind study as a whole. Their unique perspectives and insights impacted the study team's approach to every aspect of the project. The PYAs would like to highlight the following observations, many of which are echoed elsewhere in this report.

Quantitative study arm

- The quantitative study arm was only conducted in English, which means we have a very limited (Westernised) perspective on what data governance models might be acceptable globally. Non-English-speaking youth could raise many different perspectives on data governance because of the different cultural frameworks that surround these languages.
- The PYAs hypothesise that the higher than expected rate of engagement in the quantitative study arm may be because youth, in particular youth with lived experience of mental health challenges, are very driven to help find solutions to the youth mental health crisis.

Qualitative study arm

- We would have liked to test the educational materials with naive youth (i.e., youth not in a YPAG) to make sure the concepts really were understandable prior to the deliberative democracy sessions.
- Pre-specifying a set of data governance decisions (the animal models) in the educational materials was helpful in some ways but may have limited the thinking of youth and prevented them from more creative ("a la carte" style) solution finding within the seven data governance questions.
- We would have liked more capacity building about tech concepts (e.g., synthetic data set) to help facilitators feel more confident prior to the first deliberative sessions.
- The multinational round of the qualitative study arm didn't uncover much that was new and often felt redundant to facilitators and participants. In retrospect, we could have designed these sessions to push deliberantes to think more about the seven questions from a global perspective; to think more about the interrelation between the seven data governance questions; and/or to hash out a single data governance model that should be implemented by future GMHD designers.

II. Go/No Go Criteria

Area 1 Ethics and Governance

- The data governance model of the eventual GMHD needs to be be "a living breathing thing"

  - Even if there was a fixed model at the beginning of the data collection process, designers would still need to do near constant evaluation and feedback (especially at the beginning) to make sure that the model is

responsive to the real world and needs of the GMHD community (e.g., new scandals, new laws, new needs for engagement).
  ○ Also because we have a very limited sample (three countries) and the quantitative study arm was only conducted in English, we have a very limited (Westernised) perspective on what data governance models might be acceptable. Non-English speaking youth could raise much different perspectives on data governance (because of different cultural frameworks).
  ○ How do you facilitate these conversations given the timeline of building this GMHD?

Area 4 Sustainability:

● Youth do not want to generate profit for others but they do want to ensure that mental health is improved. However, there is no clear *self-sustaining* business model for a GMHD that the youth surveyed would agree to. This said, there were some hybrid models that came out of the deliberative democracy sessions that might contribute to the acceptability of an NGO-sponsored GMHD.

V. Recommendations

● Agree with the recommendations as written.
● Additionally, PYAs would like to highlight:
  ○ Nothing for us without us! Designers of the future GMHD must include youth in all aspects of their planning, design, and execution; without our participation, researchers just assume what is best for us.
    ■ We would like to highlight the myriad times the research team went back to the YPAGs for guidance. The group dynamic resulted in great ideas emerging from these consultations as well as creative solutions. Including not only individual youth, but collaborative groups of youth, will be vital to the success of the future GMHD.
  ○ Designers of the future GMHD must consider the safeguarding procedures and policies for young people within the study team (e.g., hierarchical structures, power dynamics) and for youth participants, including grievance redress mechanisms.
  ○ Designers of the future GMHD must not give voice to those who are explicitly or implicitly racist, transphobic, or otherwise unsupportive of the full spectrum of youth identity. Redress mechanisms must be specified in advance as well as procedures to remove people from the GMHD (e.g., make redundant, remove from data use, remove from data contribution).

Section IV - Project Learnings Meetings

Included in this section are key learnings discussed between the Sage and Wellcome teams which have not been represented elsewhere in the report. These learnings represent high-level insights that span the project. Given that the experiences of the sites was not homogeneous, we would recommend the designers of a future GMHD stand up a federated learning structure.

1. The Project Sponsor as a Learning Partner

Sharing of "Learnings" with the Wellcome Team was explicitly incorporated into our remit in the form of a recurring deliverable. Per the project commission, a member of the Wellcome Team (the Wellcome GMH Databank Learning Coordinator) was given access to all meetings and materials related to the commission, including recordings of meetings, except those that involved information pertaining to youth privacy and/or data.

Thus, in addition to its voting members, Steering Committee Meeting attendees included both contributing staff members at each partner organisation and members of the Wellcome Mental Health Priority Team. Members of the Wellcome MH Team attended both Steering Committee meetings and Project Team Lead Stand Ups intermittently in their capacity as "learning partners". In this role, they provided encouragement and support to project leadership, asked probing questions about project learnings and at times offered feedback for the project's consideration while refraining from offering prescriptive guidance on project decisions.

Separately, the project's lead investigators convened with members of the Wellcome team on a bi-weekly basis (1hr every 2 weeks, except meetings mutually agreed to be cancelled in observance of holidays or scheduling conflicts). By the end of the project's first quarter, the Sage and Wellcome teams agreed upon an overall aim and structure for these touchpoints, which we called "Learnings Meetings" (see Appendix IV.1. for a complete list of topics we discussed organised by meeting date).

Overall Aim: Provide frequent opportunities for deeper discussion and learning between Sage and Wellcome.

Standard Learnings Meeting topics included:
- Reviewing and getting feedback from Wellcome on a monthly progress report to be submitted by Sage.
- Learning for Sage on relevant Wellcome work and/or opportunities (e.g. offers of advice from expert advisors/ commercial agencies/ offers to speak)
- Learning for Wellcome on any particular updates that Sage elects to share (e.g. via invited project leads)
- Occasional retrospectives, when applicable

As noted in Section I.2.c., at the project's mid-point, we conducted a mixed methods survey of project staff regarding the ongoing fit of project governance structures (Appendix I.2.c.1). Among other learnings, the results of our survey highlighted a perceived connection between

the presence of Wellcome team members at Steering Committee meetings and a paucity of open, honest discourse. As one respondent shared, "there is a need to present ourselves in a different light when the contractor is in the room. We need a forum to openly share ideas and future plans." Several survey respondents also noted a lack of transparency around how project decisions were being made and who was responsible for making project decisions. Anecdotally, these feelings may have been heightened in project team members with the lowest trust and/or lowest sense of agency or power within the project. It should be considered that the reported lack of transparency around decision-making experienced by these team members may have been influenced in part by Wellcome's involvement in meetings where key decisions were being made.

2. Collection and Dissemination of Project Learnings

Though not incorporated into our stated aims for Learnings Meetings, we often used these meetings as a forum to discuss dissemination of learnings.

a. Publications Team and Publications Tracking Strategy

In the project's first quarter, Learnings Meeting attendees agreed that by the end of the project we hoped to develop a series of blogs documenting the progress of the project. To this end, we established a "Communications Sub-team," which included members of the Wellcome team, lead investigators and two volunteers representing the site leads. This sub-team's remit was to discuss and translate common learning themes arising from our Learning Meetings into regularly-occurring blog posts. We planned to address a variety of topics spanning each phase of the project from a wide range of perspectives represented on the project team. The Communications sub-team was also tasked with dissemination and amplification of each other's work.

This sub-team agreed upon an ad-hoc meeting cadence and proposed a lightweight strategy for tracking the initiation, development and coordination of all publications—both formal and informal. The proposed strategy utilised a Google spreadsheet where ideas for formal publications and blog posts would be submitted for further review by the Steering Committee and/or at weekly Project Team Lead Standup meetings. The purpose of these reviews was not to approve ideas for advancement to a next step, but to identify areas of overlap with existing work and promote collaboration across sites, project roles and areas of expertise without adding to the project team's meeting burden. Importantly, any member of the Steering Committee, including non-voting members, was welcomed to contribute to this process at every level (ideation, review, and authorship). Finally, the proposed strategy clearly identified two high-priority publications deemed essential to the project's completion (protocol and project outcomes). Due to resourcing constraints, all other publications were to be developed at the discretion of the authors and should be completed in spare time.

The proposed strategy was presented to the Steering Committee and implemented for a period of several months but for the following reasons, did not enable us to reach our stated goal for consistent dissemination of learnings.

Most evidently, resourcing constraints led us to explicitly de-prioritise frequent dissemination of results through blog posts in our strategy document. The proposed ideation process relied upon individuals to spontaneously organise themselves around self-appointed objectives and deadlines, which was not feasible. There were no project deliverables directly linked to the activities within the communications sub-team's remit, which meant that it was difficult to justify prioritising work on publications. As a result, the tracking strategy that was developed needed to be exceptionally lightweight. The sub-team did not elect to hold recurring meetings to review the spreadsheet together and none of its members took on the task of maintaining the tracking spreadsheet. Finally, the lack of a robust review process led the project team to identify additional gaps in our project governance framework related to authorship.

b. Publication Policy

Development of a formal Publications Policy for the MindKind Study (Appendix IV.2.) began in July 2021, largely in response to downstream consequences of variation in resourcing across project teams. Steering Committee members in the UK had bandwidth, experience, and resources at their disposal that enabled them to begin thinking about publications before the other site teams could. This was unintentionally not inclusive of the other teams. Team members voiced growing concerns that in the absence of a publication policy we would not be able to ensure meaningful representation of contributions of all team members while avoiding duplication of project outputs.

The final iteration of our publications policy was ratified in September 2021. It defines formal scientific publications as falling within two main groups: consortium-wide papers and topic- and/or region-specific papers. The policy prioritises consortium-wide papers over other papers, outlines a process by which all formal scientific publications are routed for approval, and provides clear parameters for determining authorship. The policy also addresses prioritisation, approval, and authorship of publications written for informal communication channels. Notably, blogs and other informal communications are deprioritized in the policy, which states they "may need to be held from publication until manuscripts are accepted for publication."

c. Recommendations

- Development of a publications policy in a large, distributed team took a significant amount of time. Therefore, we recommend that Wellcome should provide future project teams with a mandated publications policy that accounts for parity across sites and require project teams to develop a practical plan for coordination of manuscripts at the start of the project as a component of project governance.
- Equitable coordination of manuscript development is a project activity that requires a significant allocation of effort from team leads, especially in a large, distributed, multinational project team, but this work is rarely funded directly. For these reasons, it is our recommendation that future project plans should either include a deliverable or set of deliverables commissioning the dissemination of project learnings or clarify the scope of work to highlight dissemination of project learnings as out of scope.
- Researchers will need to partner with PYAs as navigators in the academic system in order to enable meaningful contributions of PYAs through authorship.

3. Unique Requirements for Remote Teaming

a. Team Building

Collaborations work best after trust has been established between participating groups. Trust building often happens naturally and relatively quickly in the face-to-face setting during normal informal interactions (e.g., coffee breaks, meals) but is difficult to engineer in a fully remote setting without committed time devoted to this purpose. Given the short timeframe scoped for this project and the global pandemic, we had no opportunities for in-person meetings and we did not commit time to remote team building during the course of this project. Doing so might have led to improved harmonisation in roles, responsibilities, and expectations, and better team communication and rapport. Because developing a future global mental health databank will be, by necessity, distributed, efforts should be made to encourage team building outside of results-oriented meetings. While in-person meetings can be used toward this end, remote team building options should still be considered since it is rarely possible for everyone on a project to travel or attend face-to-face meetings.

In order for a future global mental health databank to be successful, establishing relationships of trust between the youth, especially youth leaders and project team members, and the institution(s) sponsoring and/or directing the databank is critical. Despite regular meetings with Wellcome's Lived Experience Consultant, the PYAs began to develop feelings of distrust toward Wellcome and only at that point did the PYAs get a chance to meet with the Wellcome Learnings Partners one-on-one. We should have ensured PYAs were given regular opportunities to meet with funders, directors, and others with institutional oversight of the project to encourage their direct input and build trust. (See also "Co-design vs. Decision-making" below.)

b. Tools for Project Management & Execution

A variety of tools for collaboration, file sharing, remote meetings, and project management exist, however most face challenges in adaptation to international collaborations in which there is a disparity in electrical and digital infrastructure access and stability. Even among collaborators with no infrastructure related barriers, there were differing preferences and comfort levels with specific tools (e.g., MS Teams, Google Suite), and the lack of interoperability of these tools can make simple tasks difficult. We saw similar challenges with NVivo, the platform used for analysis of qualitative data. Future collaborations should establish use of tools that are not hindered by variable infrastructure across worldwide study teams and/or improve access and support for use of these tools.

4. Analysis of Project Risks

a. Risks to Project Scope

One point of tension within the MindKind project as a pilot study was the balance between what is ideal and what is feasible. Unfortunately, there were several points wherein collaborators, YPAG members, or other stakeholders made reasonable recommendations that were not regulatorily, logistically, or technically feasible. For example, there were a number of PYA, YPAG, and site stakeholders suggestions for app/study features that were

not feasible to implement in the short timeframe of the quantitative study arm. This tension between the ideal and the feasible led to the perception that stakeholders were not being heard. Good communication between the design and implementation teams and stakeholders highlighting prioritisation of features is essential in maintaining trust. In an ideal scenario, an iterative participant-centred design approach would be taken to incorporate a richer set of features.

Another suggestion that we received from YPAG members as well as final week survey respondents (Section I.7.e "Final Week Feedback") was to create chat functionality within the app that would enable participants to communicate with researchers or other participants. Due to the potential ethical risks of participants revealing identifying or high-risk information in these interactions, we were unable to implement this recommendation in the scope of this project, despite high desirability among youth stakeholders, although it was one of several prompts that lead to the supplemental exploratory project of tools and features to scale participatory research approaches, Bridging the Gap.

b. Risks to Project Schedule and Budget

Contracting-associated Delays to the Project Schedule

Many research institutions have rigid intellectual property (IP) policies which conflict with the multi-institution, open science/data ethos of this project. In these cases, negotiations over data and IP ownership derived from this feasibility study delayed subcontracting and project launch. Other contracting-related delays stemmed from the complexity of the type of agreements which needed to be executed for study sites involving more than one institution.

Sage notes that subaward agreements with institutions in the Global South (South Africa and India) took less time and effort to execute than agreements with institutions in the Global North (UK and US). Northern institutions allocated significant resources to the review and negotiation of IP concerns, an effort not mirrored by Southern institutions. We suspect that this is not because our Southern institutional partners are blasé about IP, but rather may be relatively resource-constrained as compared with their Northern partners. In the design and implementation of a future global mental health databank, differences in institutional resources should be accounted for in the contracting and IP negotiation process to ensure that institutions with constrained resources, and the research partners who operate within them, are not further disadvantaged or exploited as a result of systemic inequities.

Table IV.4.1: Time to Execution of Subaward Agreements by Institution

Institution	Country	Agreement Execution Month/Year
Sage Bionetworks	US	Primary Executed 23 October 2020
Centre for Mental Health Law & Policy	India	Dec 2020
Higher Health	South Africa	Jan 2021
Walter Sisulu University	South Africa	Feb 2021
University of Oxford + University of Cambridge (Tripartite Agreement)	UK	March 2021
University of Washington	US	April 2021

Impact of Delays to the Project Schedule

Due to delays in the project launch (see Section I.3.a), a "domino effect" on dependent deliverables ensued. Accordingly, youth integration in the form of PYAs and YPAGs was slower than anticipated. There were two significant impacts of project timing on PYA involvement: (1) Delays to hiring PYAs limited PYA ability to directly influence project decision-making and (2) Variation in when PYAs were hired contributed to differences in PYA roles across sites.

In India, hiring a PYA took three months and setting up a YPAG took an additional month. In South Africa, hiring a PYA took six months, plus an additional month to set up a YPAG. In the UK, hiring a PYA took five months, plus an additional two months to set up a YPAG. Of note, these timelines do not include the necessary capacity building to train PYAs in their roles on the project. As such, by the time the YPAGs were in place in all three countries, we had already made many key project decisions in order to be compliant with our deliverables and move the project forward.

Ideally, PYAs are included in the project from the outset, to ensure they have a voice in the full scope of the project (see "Co-design vs. decision-making" below).

Other project delays can be attributed primarily to legal and regulatory issues and challenges experienced during the recruiting phase of the project. These challenges are discussed in Sections I.5 and I.6.c.

Dependencies between Schedule and Budget

Team members experienced conflict between the need to compensate their staff and the need to fund recruitment innovation to achieve deliverables. Team members also voiced frustration that, despite being part of a feasibility study, there was an apparent focus by Wellcome on achieving project deliverables, leading to an impression that learnings were not sufficient to obtain compensation.

Dependencies between Sites

Site team members were also dependent on each other's success in meeting deliverables in order to be compensated. For instance, the delay in regulatory approval at the India site (see Section I.5.b "India") impacted whether the whole project team was able to hit our

project-wide launch benchmark and overall recruitment target. Variations in site staffing between sites also impacted the pace of progress toward deliverables, exacerbating between-site tensions.

Transference of Financial Risk from the Project Sponsor to the Awardee

Sage agreed to compensate subcontractors even if deliverables were not met and funds were not released by Wellcome, thus increasing Sage's risk tolerance in order to move the project forward.

c. Risks to Meaningful Engagement/Support of Young People in Research

Co-design vs. Decision-making

Lack of involvement of youth in establishment of project governance had downstream impacts on trust. In our November 2020 meeting we discussed integration of youth voice into the technical development process. At this stage, we had gained momentum on work to identify Active Ingredients, data modalities, data governance models, and data collection strategies for the quantitative study. We had also begun developing our technical strategy for alpha launch of the data collection pipeline. However, due to regulatory requirements and associated delays, we had only just begun to onboard the project's first PYA (India), and had yet to stand up any in-country YPAGs. We pivoted our strategy and stood up the ad hoc International Youth Panel. While this did allow us to get feedback from youth, it did not solve the problem that PYAs and in-country YPAGs were not able to contribute to early project decisions.

Accordingly, there is a distinction to be made between decision making (what we largely offered the YPAGs and PYAs) and the process of authentic co-design. The latter necessitates involvement from very early stages and meaningful influence over the project's trajectory. The former relationship, at times, precipitated a lack of role clarity and subsequent lack of trust from PYAs and YPAGs. Without adequate role parameters, capacity building, and demonstrated influence over project features, PYAs and their constituent YPAGs may be left wondering *What is my impact? Where do I fit in? Why should I trust that Wellcome will use my feedback?* (see "Team Building" above)

Planning for Capacity Building

We learned that if capacity building is not valued at the same level as other project deliverables, it can be neglected by those for whom capacity is already "built" (e.g., project experts). As such, when deliverables are structured around returning data rather than building youth capacity and youth partnership, the former may continue to be prioritised. At times these two aims were also in tension; the desire to make progress against project timelines sacrificed periods of time that could have been devoted to capacity building.

A timeline structure that prioritises the establishment of diverse YPAGs and supporting YPAGs with adequate capacity building may necessitate different deliverables. For these reasons, the contracting stage should include input from those with prior experience incorporating youth with lived experience as co-researchers.

SageBionetworks

Factors that Constrain Capacity Building

Traditional Academic Research and Technical Development Systems

Meaningfully integrating youth requires additional time being factored into the project relative to traditional research timelines (see "Co-design versus Decision-Making" above). In the case of this project, decisions that are typically made within discrete research teams required vetting by youth members across the sites. This resulted in extra time for each step/decision to inform PYAs, facilitate PYA capacity building, and for PYAs to convene YPAGs.

Integrating youth into working meetings may have been one approach to speed up the technical development process in this project, however logistical challenges existed to finding times that work for the Pacific-based research and tech development teams and the PYAs in India, South Africa, and the UK.

Tight timelines created a tension between researchers and PYAs/YPAGs. PYAs and YPAGs at times reported pressure to provide immediate feedback when they would have preferred space to sit with information. As such, the demand for speed to meet project deliverables was not compatible with the needs of youth.

This phenomenon was further exacerbated by inherent tensions between agile development–an approach to technology project management–and traditional research practices. While agile processes are designed to be adaptive to allow for the integration of stakeholder feedback, they can create tensions with the regulatory requirements for research. Moreover, regulatory requirements themselves were in tension with youth stakeholder feedback. While regulatory guidelines necessitate "nailing down" protocols and executing them, meaningful youth stakeholder engagement often necessitates iteration and evolution of ideas. This tension would be alleviated by allowing a longer design/co-design phase.

Relationship between Team Resourcing and Capacity Building

Staffing disparities between teams created other disparities downstream. Differences in capacity, staffing redundancy, and working hours between site teams were persistent throughout the life of the project. Due to this "starting line disadvantage," researchers at lower resourced sites were not always able to translate data into insights as quickly as researchers at higher resourced sites.

These staffing disparities affected the PYAs and YPAGs as well. Variations in how teams were staffed beyond the PYA role contributed to variation in expectations of the PYA depending on the site. This dynamic further contributed to the lack of role clarity felt by YPAs. Furthermore, to maintain YPAGs with greater diversity in languages, cultures, and resource access is a more laborious undertaking than "convenience sample" YPAGs. While diverse YPAGs enable richer feedback, staffing constraints can prevent these YPAGs from being stood up.

Section V - Requirements for a future global databank

There are four motifs that frame our requirements for a future global mental health databank: equity/global inequity, the tensions between the risks and benefits of data sharing, sources of bias in the data collected, and the role(s) of youth in the future GMHD (Figure V.a.). At the highest level, these motifs must be accounted for in any GMHD planning, development, implementation, and analysis efforts.
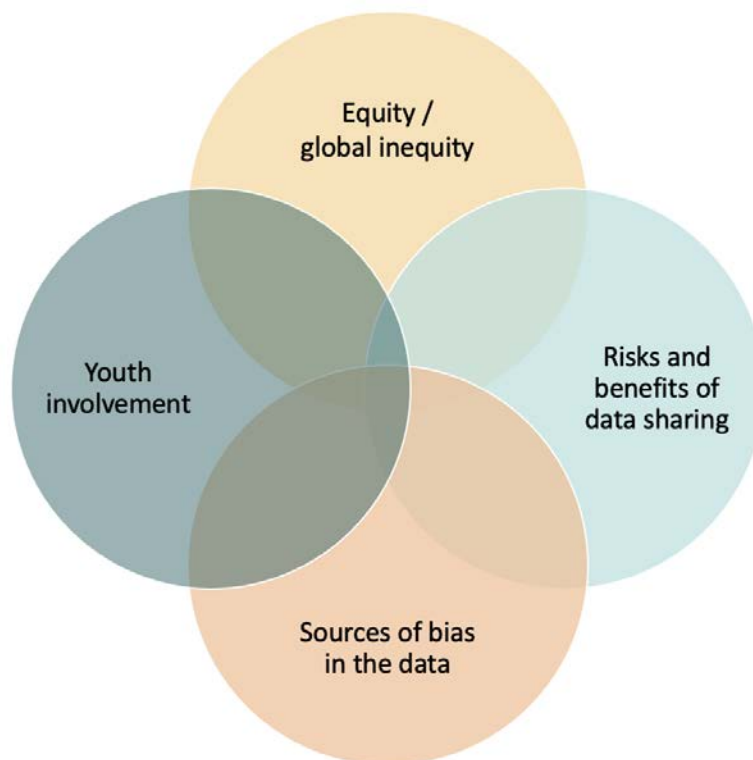

Figure V.a: Motifs for a global mental health databank

Requirement 1: Infrastructure

Global digital infrastructure disparities were a significant impediment to the equitable conduct of this project. The relative cost of technology varies widely around the world, leading to critical differences in ease of access and diversity of participants for digital health studies. The MindKind PYAs suggest a digital equity fund (see I.3.b. Recommendations) for the future GMHD to help compensate for these disparities.

The impact of the cost of entirely virtual participation extended even to PYA members of the study team themselves. Budgeting and project governance often failed to account for the cost and/or logistics of timely pre-payment for digital tools to host virtual YPAGs, the data required for regular participation in project meetings, as well the financial barriers to post-study PYA involvement (for example in manuscript preparation).

Further, we observed data loss due to the instability of in-country internet networks. Designers of future GMHD data collection systems will need to account for network instability in data harvest procedures.

Youth in the UK from diverse economic backgrounds had relatively ready access to devices, newer models of devices, and reliable internet. This said, the quantitative study was hosted only on the Android platform, and Android devices make up a relatively small percentage of the overall youth smartphone market in the UK.

In India, although fewer youth from diverse economic backgrounds had access to their own device or newer models of devices, mobile phone data is relatively inexpensive and fairly reliable–we saw the least evidence for data loss in India.

In South Africa, mobile data is relatively costly as are devices. To account, in part, for this disparity, we planned that all participants would be compensated for data used in the study. This was difficult to implement because of local bureaucratic challenges. Access to reliable internet and, at times, reliable electricity was a significant challenge even for study team members based in South Africa.

Requirement 2: Opposition to commoditization of data

The majority of participants in the qualitative and quantitative MindKind study arms are fundamentally opposed to their data being treated as a commodity. Any self-sustaining business model for a GMHD would conceivably depend on commoditizing the data it contained in some way. The business model of the databank will impact on who joins, who contributes, what they contribute, and/or for how long to a future GMHD. Please see Section II. Go/No Go Criteria, Area 4: Sustainability for further discussion of our findings.

Requirement 3: The role of youth

Youth were integral to the success of this project: as members of the study team, as advisors to the project, and as data contributors. Despite significant evidence that youth from each of these cohorts felt their voice was heard, there was still dissatisfaction among youth and within the research team about the limits of youth engagement. In short, young people were decision makers but were not fully engaged as co-designers. Developers of the future GMHD will need to weigh the benefits of youth agency in a GMHD that results from co-design with the time and effort required for true co-design and the potential knock on impact of youth co-design on the scientific utility of the future GMHD.

Requirement 4: Governance model considerations

Sandboxing

Youth expressed a strong preference against data download, favouring sandboxing for their banked data. If the future GMHD is to adopt a sandboxing approach to data stewardship, Wellcome will need to investigate further what tools and supports are needed to architect a data sandbox for researchers with lower computational skills

and/or intermittent or limited bandwidth internet access. This is considered a critical equity issue by the study team, especially the PYA.

The anonymity arms race

Researchers are engaged in an anonymity arms race: as solving methods advance, so too does our ability to re-identify previously anonymous participants. This concern is arguably heightened in more open data stewardship approaches.

There was a consistent tension observed in the qualitative study arm deliberations between desire to share data to help improve mental health and with fear of losing anonymity–even a fatalistic non-believe in digital anonymity generally.

This tension is mirrored in the rapidly evolving regulatory environment for data collection, storage, and use including cross-border data transfer, privacy, and notification and consent.

The future GMHD will need to account for these tensions and plan for this dynamic reality.

Data stewardship

Beyond a preference for data stewards to be compensated, there remains ambiguity about the preferred identity and roles of data stewards.

Requirement 5: Barriers and incentives to participation

Language

The quantitative study arm's app and website were available only in English. This significantly limited who could be included in the study. We hypothesise that the steep drop off of youth in India during the consent flow, app download, and engagement may be due at least in part to the high level of fluency needed to understand and participate in the quantitative study arm.

In South Africa, qualitative study arm discussions were held predominantly in English. Limited English fluencency, especially for complex and unfamiliar terms and topics associated with data governance, may have contributed to some South African participants' lack of detailed feedback. For example, when asked to share the thinking behind their yes or no answer, some youth would change their answer rather than elaborate.

Future GMHD designers will need to consider proactively the impact of a single-language platform against the time and effort needed to host platforms in multiple languages.

Recruitment

The site teams spent a tremendous amount of effort to identify effective recruitment strategies. Larger scale efforts are unlikely to be successful without in-country study teams developing customised materials and approaches on an ongoing basis. These

local teams will also be crucial in developing future strategies to minimise bias and improve access.

Overall engagement, compensation, and equity

As noted in section I.6.e, we see slightly higher engagement than a similar *uncompensated* mobile study of mental health (Start), but substantially lower engagement than the *compensated* study, Brighten. While we don't know the factors influencing the effect of the former, it seems likely that compensation in future studies may improve engagement, with previous evidence suggesting compensation can increase participation more than 10-fold[1] in US-based cohorts.

Of note, compensation may be reframed as an equity and access issue. In South Africa the study team used data payment to remove a barrier to participation, adjusting for digital inequity, rather than as a form of individual-level compensation per se.

The MindKind quantitative arm data are heavily biassed, overrepresenting youth with lived experience, women, youth with digital access (both in terms of device access and internet access). At minimum, designers of the future GMHD will need to develop strategies to describe biases and ideally seek pathways to reducing bias in data collection. Designers should seriously consider a digital equity fund and/or compensation. They could also assess the role of demographic-sensitive branding and funding targeted, local outreach efforts.

Cross-country differences

We observed significant cross-country differences in enrollment and engagement rates. More work is required to uncover the reason for these differences and develop strategies to mitigate them.

Non-monetary approaches to improve engagement

In addition to monetary compensation, there are a number of strategies to potentially improve engagement that were outside the scope of this feasibility study. Participants reaching the end of the study noted that they found value in reflecting on their mental health. However, there are potentially more ways to make the app more useful, provide more value to participants, or otherwise make the experience more fun. These include:

> **Reminders and scheduling**
> - Use of reminders, scheduling features, etc to encourage daily engagement
> - Feature to "pause" study participation (e.g. during exam time) and resume at a more amenable time
>
> **Access**
> - Development of multiple platforms (Android, iOS, web) to improve access

- Strategies to mitigate access issues for those without their own device or who face infrastructure-based barriers

Value for participants
- Return of results to participants in the form of retrospective graphs of change over time and comparison to past results
- Interesting mental health related tips, research, or general fun facts
- Explore the possibility of Bridging the Gap-style networking features, with appropriate safeguarding of participants (which would add value for researchers as well as for participants)

App design
- Continued use of popular (cheerful) elements like use of gifs
- More visual design elements (e.g., emojis for mood) and general improvement of app visual appeal
- More interactive app features, as well as thoughtful gamification to make participation more engaging

Data collection protocol

While early testing of the surveys in the protocol found them to be well-tolerated, some participants reaching the end of the study reported that they could be monotonous and the weekly surveys could be burdensome. Future effort should include a focus on optimising the survey protocol.

Surprisingly, giving participants a choice of AI was detrimental to engagement. Future studies should provide a fixed (i.e., not participant selected) set of AI topics, though good study design would suggest that randomising the order of presentation is still warranted.

Future work on the AI topics presented is also suggested. Participants in our study had a strong preference for Sleep and Social Activities over Body Movement and Positive Experiences, though overall participation within these topics was similar once assigned. Additional inquiry can examine whether there are better ways to present/query these topics.

These four topics were selected from among dozens previously shown to affect mental health[2], however future studies could integrate more of these.

Requirement 6: Local adaptation

Cultural differences, equity, and social justice were key themes within the project. Designers of a future GMHD will need to weigh the benefits and drawbacks of an equality approach (the same experience everywhere) with an equity driven approach (local, tailored) both scientifically and in the context of engagement. Designers will need to ensure they account for the time and effort required to appropriately adapt to local contexts. Local study teams will be critical to this effort as will including youth members in these study teams.

Section VI - Specifications for an "ideal" GMHD

Based on the analysis of the data collected in this study as well as the expertise of the consortium members, we highlight the following specifications for the future global mental health databank. It is important to note that these specifications are suggested unconstrained by pragmatic considerations like time or effort and, as such, some specifications may be more or less feasible to implement.

1. Data governance specifications

 a. Data housed in the GMHD should be accessible to researchers broadly, including citizen or community scientists
- All people accessing the databank would be treated equally (no fast track for academic researchers)
- There would be no artificial barriers to its use (for example, credentials that are only available to academic researchers)
- To provide recompense in cases of research misconduct, consider a bonding/insurance system for all researchers using the GMHD. This system, similar to tradesperson bonding/insurance, would be invoked in the case of researcher misconduct, with fees being applied directly to the benefit of any community harmed by research misconduct.
  - In the US and many other parts of the world, institutional affiliation serves as a proxy bonding/insurance system for researchers (and the lack of institutional affiliation as one of the key barriers to citizen- and community-based scientists accessing data resources). In cases of researcher misconduct the institution employing the researcher is sanctioned with recompense rarely flowing back to the community that has been harmed. For this reason a bonding/insurance system would be more just for the communities contributing data as well as for researchers accessing the resource.
    - Any bonding/insurance system would need to be implemented in such a way that it did not itself become a barrier to researchers in lower resourced areas and/or citizen- or community-based scientists.
- There would be supports for community based researchers' use of the data including free/low cost data science consultation and support
  - The GMHD landing page should have an easy-to-use data browser that, in plain language, displays aggregate findings for citizen scientists and interested community members to learn about mental health insights.

 b. As much as possible, data should be federated
- All identified data would be held in its country of origin to ease regulatory compliance and reduce barriers to data collection.
- Deidentified data could remain federated or move to a central repository, although given the rapidly evolving regulatory environment, there may be regulatory prohibitions or requirements that make a centralised de-identified data repository a less tenable option.

- If deidentified data were to remain federated, it would still need to be moved centrally for multi-country analysis. These systems would be flexible and transparent to allow for regulatory compliance, and the attendant researcher interface for multinational data would need to be designed to feel seamless for the researcher themselves. This design is contingent on identifying technical solutions to allow this on-demand transfer at-scale to make this approach feasible.

c. Data should be housed on a server (sandboxed) and be designed for access by those with low bandwidth/intermittent internet access as well as for those with developing computational skills.
   - As benchmarking standards on synthetic datasets progress, a synthetic data option could be made available so long as it is sufficiently representative of the underlying data.

d. A paid community review panel should guide data use by setting data use options that participants consent to within the study and/or by drafting and enforcing data access requirements and/or data use guidelines for researchers. This paid panel would be comprised of representatives from each participating country's own local data collection and use panel. The local panel members would also be paid for their work.
   - This two layered structure would be similar to our YPAG structure which resulted in wisdom and creative solution finding from the *group* (rather than relying on single persons as representatives) (See Section III for further discussion).
   - To guard against conflicts-of-interest or undue influence, panellists would be employed through the central databank and not by local site partners. Alternatively, there would be contracting in place that would allow for central requirements/support to panellists.
   - The paid community review panel would have inbuilt mechanisms for evaluation of databank governance and reengagement of those banking their data on a periodic basis. The panel would also create protocols for rapid databank safeguarding, ensuring responsiveness to data governance news stories that damage participant trust or events of data governance breach.

e. There should be no fee for accessing the data except to commercial companies. In order to access data, researchers would have to a) complete ethics training hosted by the GMHD, b) provide evidence of their identity, c) attest that they will abide by the data use rules of the GMHD, and d) submit their research for review by a GMHD-dedicated ethics committee.
   - There could be an ethics committee dedicated to the GMHD but independent from it, recognized by each of the ethics authorities in each participating country, that includes community members, is free to researchers, and is highly efficient with low bureaucratic friction.
      - Lessons can be taken from the US *All of Us* Research Program and similar large scale databanking initiatives around the world, many of which have set up similar systems.
      - We advocate for the use of a central, independent ethics committee to reduce the risk of corruption playing a role in data access (a primary concern of some MindKind youth participants). Researchers may still be required by local law to submit their proposed research for review

by their local research ethics body–although the future GMHD designers should explore reliance agreements (like those used to enable central IRB review for consortia in the US and many other countries) with those authorities to allow for the GMHD to be the single ethics committee of record.

f. The GMHD should be funded by a non-profit organisation or consortium in perpetuity. Commercial fees for its use will be contributed to the running of the GMHD but the data will not be able to be controlled or used for profit making by the commercial entities.

g. No matter how tempting it would be to allow all kinds of research, because certainly this resource could power myriad insights, the GMHD should allow research on mental health only.

   ○ What constitutes "mental health" could be arbitrated by the paid community review panel (#4, above) and/or could be put to periodic vote by the data contributors such that the definition is community sourced and could evolve over time.

2. Study design specifications

a. GMHD designers should allocate sufficient time and resources for:
   ○ For an iterative, youth-driven design process for both the study app and survey instruments.
   ○ For instrument design and testing in each new locale.
   ○ For testing of study technology in each new locale to identify locale-specific technical issues prior to launch.

b. In order to reduce bias in the dataset itself the GMHD, designers should:
   ○ Develop mechanisms to ensure the safe, meaningful participation of gender diverse people as well as young men, the latter of whom were underrepresented in our study.
   ○ Implement strategies for incorporating youth whose infrastructure or access to devices would otherwise exclude them.
   ○ Ensure study participation and dissemination materials are available in many languages, prioritising languages in the Global South.

c. In order to increase the reliability of the insights gained from the GMHD, designers should:
   ○ Employ in-country research teams for the length of the project such that they can reassess recruitment strategies, identify sources of bias and implement mitigation strategies, and address related recruitment issues on a periodic or ongoing basis.
   ○ Encourage the participation of those *without* lived experience of mental health challenges.
   ○ Audit and assess the scientific content of the GMHD on a periodic and regular basis:
      ■ Are there areas that have not been fruitful that should be removed?
      ■ Are there new areas of inquiry to include?

3. Additional design specifications

a. Designers should implement and assess participatory research at scale tools/features into the GMHD, such as those described in the Bridging the Gap supplemental project
   - Youth/researcher co-analysis tools and features should be prioritised.
b. The GMHD should be designed with an eye to accept all types of data (e.g. incorporation of outside data, inclusion of data from biological samples, etc).
   - Be prepared to fund local biospecimen cores to generate biosample data to serve both regulatory compliance and capacity building/knowledge sharing goals.

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