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Acceptability and feasibility of a multidomain harmonized data collection protocol in youth mental health

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Abstract

Objective: To develop targeted treatment for young people experiencing mental illness, a better understanding of the biological, psychological, and social changes is required, particularly during the early stages of illness. To do this, large datasets need to be collected using standardized methods. A harmonized data collection protocol was tested in a youth mental health research setting to determine its acceptability and feasibility.

Method: Eighteen participants completed the harmonization protocol, including a clinical interview, self-report measures, neurocognitive measures, and mock assessments of magnetic resonance imaging (MRI) and blood. The feasibility of the protocol was assessed by recording recruitment rates, study withdrawals, missing data, and protocol deviations. Subjective responses from participant surveys and focus groups were used to examine the acceptability of the protocol.

Results: Twenty-eight young people were approached, 18 consented, and four did not complete the study. Most participants reported positive subjective impressions of the protocol as a whole and showed interest in participating in the study again, if given the opportunity. Participants generally perceived the MRI and neurocognitive tasks as interesting and suggested that the assessment of clinical presentation could be shortened.

Conclusion: Overall, the harmonized data collection protocol appeared to be feasible and generally well-accepted by participants. With a majority of participants finding the assessment of clinical presentation too long and repetitive, the authors have made suggestions to shorten the self-reports. The broader implementation of this protocol could allow researchers to create large datasets and better understand how psychopathological and neurobiological changes occur in young people with mental ill-health.

KEYWORDS
data sharing, harmonization, transdiagnostic, youth participation

1 | INTRODUCTION

In our recent publication (Lavoie et al., 2019), it was argued that large, multi-centre datasets are needed to better understand the psychopathology and neurobiology of mental-ill health, and to develop more targeted treatment. One method of populating these datasets is the harmonization of data collection, which can enable more efficient data sharing and sample generalisability (Hamilton et al., 2011). This can also increase the statistical power of pooled datasets, enabling researchers to address novel research questions that cannot be addressed using data from a single study (Roberts & Binder, 2009).

A harmonized data collection protocol (Lavoie et al., 2019) was proposed with the aim to standardize data collection across youth mental health research in Australia. The suggested protocol includes measures focusing on four main domains (clinical presentation, neurocognition, neuroimaging, and biospecimens), which were selected based on their potential to provide biomarkers to psychiatric illnesses (McGorry et al., 2014). Measures were selected by four panels of experts in youth mental health, members of the Neurobiology in Youth Mental Health Partnership (NYMHP). Focus was on collecting the most pertinent and useful information in the least amount of time possible. Assessments also needed to be applicable across diagnoses and relevant to young people aged 12–25 years.

The aim of the current study was to assess the feasibility and acceptability of the NYMHP protocol in young people with mental ill-health. It was hypothesised that the NYMHP protocol would be (1) feasible, as assessed by recruitment rate, missing data, protocol deviations, and study withdrawals, and (2) acceptable, as subjectively assessed by participants.

2 | METHOD

2.1 | Participants

Participants were recruited from Orygen Specialist Programs, a public youth mental health service located in the north-west suburbs of Melbourne, Australia. Participants were recruited from the four specialist clinics: Early Psychosis Prevention and Intervention Centre (EPPIC; psychosis), Helping Young People Early (HYPE; personality disorders), Personal Assessment and Crisis Evaluation (PACE; at risk for psychosis), and Youth Mood Clinic (YMC; depression, bipolar disorder, anxiety).

Given the sample size recommendations for feasibility aims depend on the nature of the study, it was suggested that samples as small as 10–15 are sufficient (Hertzog, 2008). Due to the highly subjective nature of the data collected in this study, the target sample was set to 18 participants.

Participants were considered for inclusion if they were current clients at one of the four specialist clinics and aged 15–25 years (inclusive). Exclusion criteria included documented history of intellectual disability and/or developmental delay, poor command of the English language, and high risk to self or others. Written informed consent was obtained from participants, and parental or guardian consent was received for those younger than 18 years. The study was approved by the Melbourne Health Human Research Ethics Committee (2019.194). Participants were reimbursed for their time dedicated to their participation in the study.

2.2 | NYMHP battery

Panels of experts were formed to work on four specific areas: clinical presentation, neurocognition, neuroimaging and biospecimens. Panel members met face-to-face, via teleconference or through emails over a period of 2 years, in order to reach consensus within each domain. The technique used to reach consensus was a variant of the Nominal Group Technique, whereby participants were asked to answer the following question: 'If you had 30 min with a research participant, what assessments would you conduct?' The battery was to provide a comprehensive neurobiological, psychological, and neurocognitive snapshot of a given individual at a given point in time regardless of their clinical presentation. For a full list of measures included in each domain, see Table S1 and Lavoie et al. (2019).

2.2.1 | Clinical presentation and neurocognitive tasks

Clinical presentation (i.e., mental health state and functioning) was assessed during an interview and using a series of self-report questionnaires.

The neurocognitive battery was presented on a laptop and facilitated by the researcher.

Given the current feasibility study did not intend to analyse MRI data, it was considered unethical to collect MRI data with no intention of data analysis. Due to this, a mock MRI, instead of a real MRI was used. Prior to the mock scan, participants were given detailed information about the procedure. Participants were asked to lay on the scanner table, which was moved into the mock scanner. Noise-cancelling headphones were provided due to the loud sounds produced by the mock scanner. Participants remained in the scanner for 10–15 min while watching a movie and they were continuously monitored throughout the procedure.

2.2.2 | Mock blood test

Similar to the MRI scan, the current study did not aim to analyse real blood samples. Therefore, mock blood tests, instead of real tests, were performed to ensure ethical conduct of research. Participants were taken to a phlebotomy room where they were invited to sit in the sample collection chair. A researcher explained the two blood sampling procedures (dried blood spot and venepuncture), in accessible language. For the dried blood spot explanation, participants were presented with a segment (between 0:50 and 1:50) of a video found at

https://www.myhealthtest.com/collecting-a-sample. A real finger prick device and needle were shown to participants. For the mock venepuncture, the researcher explained the fasting protocol and blood sampling procedure, while showing one blood collection tube and butterfly needle.

All assessments were conducted by the same researcher (SY).

2.3 | Acceptability measures

2.3.1 | Surveys

After completing each assessment (i.e., clinical research interview, self-reports, neurocognitive tasks, mock MRI, and mock blood test), participants were asked to complete a short survey to provide feedback on the assessment. Examples of questions included: How safe did your feel during the assessment? Was it too long? Did you find it interesting? Any other comments?

2.3.2 | Focus groups

At the end of the data collection period, participants were invited to take part in focus groups during which they were asked to give feedback about the study and provide suggestions to improve the protocol. Open questions, similar to those in the surveys, were asked to participants in a semi-structured matter. A safe and welcoming environment was provided to facilitate an open discussion. These sessions were to enrich the information collected using the surveys and it was not intended to conduct qualitative analyses on the information collected. The focus groups were moderated by SY and SL. All sessions were completed online, via Zoom.

3 | RESULTS

3.1 | Participants

Five participants recruited from PACE were considered at risk of developing a psychotic disorder, five EPPIC clients were experiencing a first episode of psychosis, four young people recruited from HYPE presented with a borderline personality disorder and four young people diagnosed with major depressive and/or anxiety disorder were recruited from YMC. Mean age (± standard deviation) was 20 ± 2.1 years.

3.2 | Feasibility

Figure 1 shows the flow of participants into the study. After the prescreening process, 28 young people were approached for participation in the study via text message and phone call. A total of 18 participants were included in the study, giving a recruitment rate of 64.3%. Participants were aged between 16 and 23 years, with 50% identifying as females, 38.9% as males, one person as non-binary and one person preferred not to say. Three participants withdrew from the study, and one was lost to follow-up, giving an attrition rate of 22%. A further two people only partially completed the surveys (see Table S2).

Due to government restrictions during the COVID-19 pandemic, most assessments of clinical presentation were completed via Telehealth and the remaining tasks were completed in person at a later date when they were permitted. As a result, the time between clinical assessments and the remaining tasks ranged between 155 and 279 days.

It took, on average, 65 min to complete the clinical assessment, 32 min to fill out the self-reports, 32 min to complete the neurocognitive tasks, around 10 min to demonstrate the mock blood test, and participants remained in the mock MRI for 10–15 min.

3.3 | Acceptability: Results from the surveys

3.3.1 | Clinical interview (Figure S1)

The clinical research interview was conducted online via Telehealth, for 17 participants, and in person for one of the participants.

Twelve (70.5%) participants agreed that the clinical interview was interesting, while one thought that it was stressful. A majority of participants (82.4%, $n = 14$) reported that they felt safe during the interview. Two participants (11.8%) agreed that there were too many questions, and it was 'boring'. A majority of participants (64.7%, $n = 11$) stated they would participate in the interview again if given another opportunity.

One participant suggested conducting the interview in person to avoid technical issues. '*Though sometimes it's nice to be in the safety of your own home during something unfamiliar like this, so maybe a phone interview could be an option*'. Two participants suggested having fewer and less repetitive questions.

3.3.2 | Self-reports (Figure S2)

Four participants (33.3%) found the self-reports interesting, one found them stressful, and four (33.3%) thought that there were too many questions. Most participants (83.4%, $n = 10$) reported feeling safe whilst completing the self-reports. Seven (58.4%) participants agreed to complete the self-reports again if given the opportunity.

3.3.3 | Neurocognitive tasks (Figure S3)

The majority of participants who completed the neurocognitive tasks (78.5%, $n = 11$) agreed that the neurocognitive tasks were interesting and 12 (85.7%) reported that they felt safe. Three (21.4%) participants reported that it was stressful, two (14.3%) agreed that there were too many questions, and one (7.1%) reported that it was 'boring'. Nine

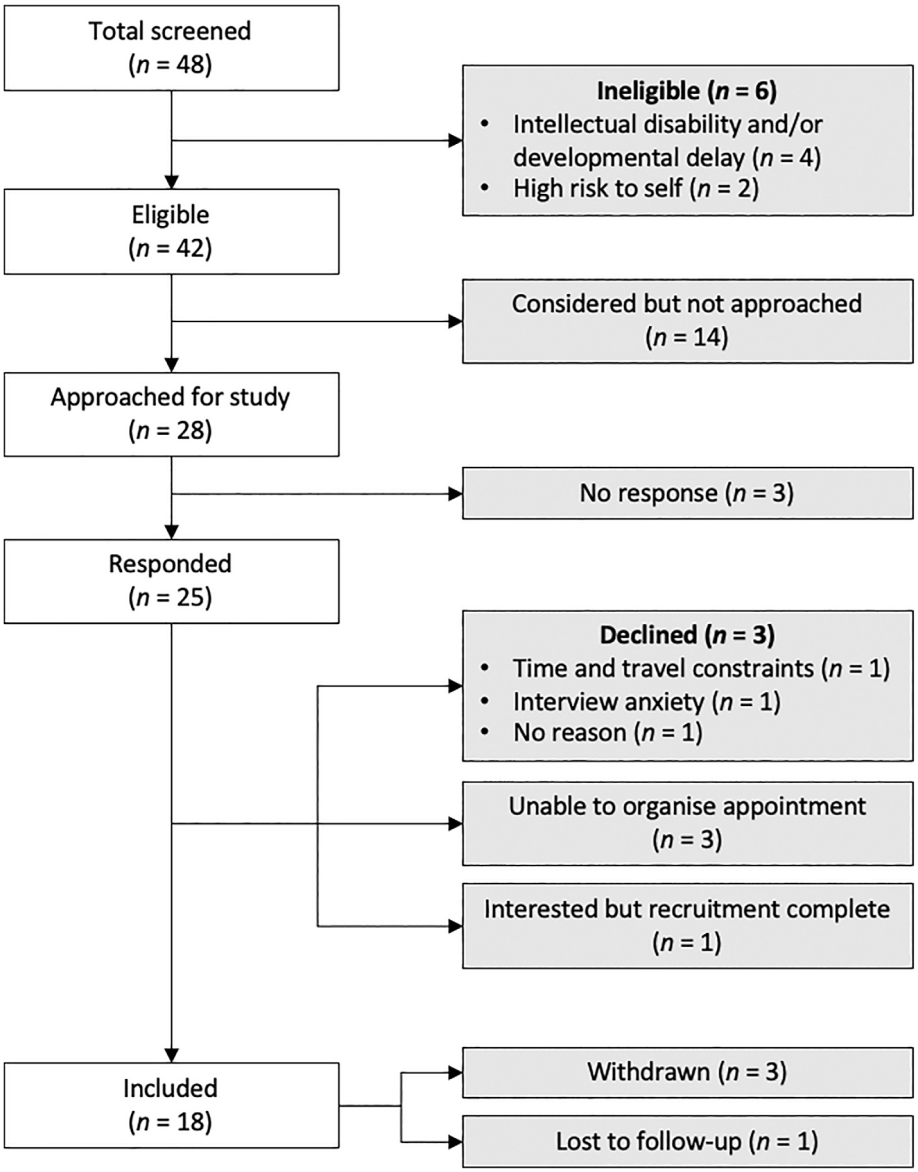

FIGURE 1 Flow of participants into the study

(64.3%) participants agreed that they would complete the neurocognitive tasks again if they were given another opportunity.

Additional feedback included the simplification of tasks: '*touch screen for the maze, have the cards go left for no and right for yes to keep a consistent understanding of which button is which*'.

3.3.4 | Mock bloods (Figure S4)

Nine (64.3%) participants agreed that the mock blood test was interesting. One participant reported that the mock blood test was stressful and that they felt scared or anxious. One participant expressed concerns regarding the assessment, specifically that there were too many samples being collected. If they were given an opportunity to complete a real blood test for research, most stated they would agree to participate (78.6%), and 85.7% stated they would be willing to fast for 12 h overnight before the blood test.

One participant mentioned that the finger prick method appeared painful, while two others gave feedback suggesting that they were comfortable with the process: '*I felt safe and comfortable throughout the mock blood test. I have no further suggestions*'.

3.3.5 | Mock MRI (Figure S5)

Most participants agreed that the mock MRI was interesting (78.6%) and that they felt safe in the scanner (85.7%). No one reported that the mock MRI was stressful, too long, or 'boring'. The majority of participants stated they would agree to complete a real MRI (85.7%) if they were given the opportunity. One participant said they would not participate in a real MRI for research, due to time constraints.

When asked for feedback on the MRI session, responses received included the following: '*the movie blocks most sounds from the machine, and it was a good distraction*'; '*I felt comfortable and safe throughout*

TABLE 1 Survey responses for questions regarding the overall protocol

Type of assessment	Interesting (%)	Felt safe (%)	Would do again (%)	Stressful (%)	Too long (%)	Boring (%)	Difficult to commit (%)	Interfered with life (%)
Clinical interview	70.6	82.4	64.7	5.9	11.8	11.8	0	5.9
Self-reports	33.3	83.3	58.3	8.3	33.3	41.7	8.3	16.7
Neurocognitive	78.6	85.7	64.3	21.4	14.3	7.1	0	0
Mock blood	64.3	78.6	78.6	7.1	7.1	N/A	0	7.1
Mock MRI	78.6	85.7	85.7	0	0	0	0	0

Note: Percentage of participants who responded 'agree' or 'strongly agree' to each item.

the process and have no additional suggestions'. One participant expressed concern that the MRI sounds may be damaging.

3.3.6 | Overall study survey

Table 1 shows that overall, participants felt safe while completing each of the assessments. The clinical interview, neurocognitive battery and MRI were perceived as relatively more interesting than the self-reports or blood tests. The self-reports were often perceived as too long and boring. Most participants stated they would participate in the study again if given the opportunity. Time commitment was not an issue for those participants who completed the assessments.

Participants were asked for suggestions on how to improve the research experience, a few participants said: '*I wouldn't change anything as it was all cohesive*'. Some common themes were identified when participants were asked about the benefits of participating in the study: '*partaking and assisting in the advancement of mental health care*'; '*to help people*'; '*contribution to science and discovery*'. A few participants mentioned that the reimbursement was a benefit for them.

3.3.7 | Focus groups

Eight people participated in one of the three 1-h focus groups that were conducted. Most participants reported that the study was interesting and straightforward: '*interesting study*'; '*efficiently conducted, was very comfortable, felt safe*'; '*it was relaxed, no stress*'.

Some participants found it challenging to complete the assessments over multiple sessions throughout the year: '*can't really remember the specific content of the previous sessions*'. They suggested contacting participants in between assessments, with a study summary and reminder of what assessments are remaining.

Some participants preferred completing the self-reports in person: '*would do it faster in person. Might lose track if I need do it by myself*', while others preferred to complete the task during their own time: '*like to do it at home at my own pace, so I can take a break. Would not like to sit with the researcher and feel forced to do it, would induce stress*'.

Many participants suggested that the results of their neurocognitive tasks should be shared following conclusion of the study: '*feedback – get the results from the neuros and also report at the end*'; '*would like to know the expected outcome and results*'.

4 | DISCUSSION

The current study examined the feasibility and acceptability of the NYMHP protocol, proposed by Lavoie et al. (2019), in Australian young people with mental-ill health. Overall, the protocol appeared to be feasible and well-accepted by participants.

The feasibility of the NYMHP protocol was determined based on recruitment rates, study withdrawals, missing data, and protocol deviations. The target sample size, that is, $n = 18$, was reached in 17 weeks, which represents one participant recruited per week on average. Encouragingly, the limiting factor in the speed of recruitment of participants was not the availability of potential participants or the difficulty of recruiting them, but rather the availability of the part-time researcher. The recruitment rate, as defined by the proportion of approached potential participants who consented to the study, was 64.3%. There is a general consensus that recruitment rates of 70% and above are necessary to ensure that the obtained sample group is sufficiently representative of the target population from which its members are drawn, that is, low recruitment rates are associated with non-response bias (Patel et al., 2003). A recruitment rate of 64.3% is therefore somewhat low and the sample included in this project may not be entirely representative of the Orygen clients' community. However, one of the young people approached was interested to participate however, by the time the appointment could be organized, the target sample size had been reached. Had this person been included, the recruitment rate would have climbed to 67.8%.

Four people did not complete the study, giving an attrition rate of 22%. Recruitment into the study, clinical interview, and self-reports could be conducted via Telehealth or online during COVID-19-related restrictions. However, participants had to be recontacted up to 9 months later to complete the in-person assessments. At this later point in time, two participants confirmed that their situation had changed since they were recruited in the study, one participant had lost interest and one person was lost to follow-up. In longitudinal mental health studies, attrition is well known to be high due to general decrease in motivation, lack of mobility, prevalence of morbidity, and even mortality rates (Salthouse, 2014). However, in cross-sectional studies, these reasons are usually not an issue. It is therefore expected

that if assessments were not delayed due to COVID-19 restrictions, there would have been no attrition for the current study. Given this deviation was not due to study limitations, it does not undermine the feasibility of the study.

Amongst the participants who completed the study, a majority reported that the time commitment was acceptable and that it did not interfere with aspects of their life. This was true even when assessments were completed at two different sites, with some participants having to travel up to 4 h to complete the assessments. Several participants acknowledged the benefits of participating in research. Participants stated that they wanted to help people, contribute to research, and support the improvement of mental health care.

Two participants partially filled out the self-report questionnaires. The length of the questionnaires may have led to the missing data, as confirmed through participant feedback from surveys. However, it appears that these two participants experienced a technical issue and although resolved immediately, they did not return to complete the questionnaires. Furthermore, the results suggest that it is important to provide different options for completing the self-report questionnaire, as some participants preferred an online link, while others preferred in-person completion in the presence of the researcher.

When booking in-person assessments following the COVID-19 lockdowns, many participants reported not remembering what the study was about. This is an important consideration for studies with long follow-up periods, and it should not be assumed that participants will remember why researchers are contacting them following months of inactivity. Study teams should also consider between-visit engagement communications.

To assess the acceptability of the protocol, we examined participants' subjective responses from qualitative surveys. Nearly all participants reported feeling safe during all assessments and all participants felt comfortable with the research staff. Out of all the assessments, the mock MRI was favoured, and participants found it interesting and not stressful. This is an extremely important finding because in research settings, it is often assumed that MRI scans are perceived as distressing and burdensome by participants. However, in our study, most participants found the mock MRI interesting and felt safe during the procedure. Participants emphasized the importance of explaining the procedure in detail in lay language and receiving these explanations multiple times if needed prior to the scheduled appointment as well as during the procedure.

Many participants expressed that the clinical interview and self-reports were interesting, but also stressful and too long. These assessments lasted on average 65 and 32 min, respectively, which are relatively short times compared to many studies in the field of mental health. Researchers will need to consider these factors when working with young people, as an MRI may be more enjoyable and interesting than lengthy interviews and repetitive tasks. Participants expressed dislike of repetition across questionnaires or within the clinical interview. Incorporating this feedback, the authors suggest changes to the self-report questionnaires, noting that shorter questionnaires may come with their own disadvantages (see Supporting Information).

Most participants found the neurocognitive tasks interesting and were almost unanimous in expressing that they would have liked to see their results following completion of the tasks. This is consistent with a body of research which demonstrates that receiving research results is preferred by participants (Dixon-Woods et al., 2006; Long et al., 2016; Partridge et al., 2005; Shalowitz & Miller, 2008). Researchers may consider providing research participants with a short report presenting not only the group results, but also the individual results in the context of the average population. Any abnormalities in individual results may need to be introduced, explained and possibly followed-up by a clinical practitioner.

The current study has several strengths. First, the study included numerous surveys to gather thorough feedback from participants (general survey for the overall protocol and study, and separate surveys for each assessment, i.e., clinical interview, self-reports, neurocognitive tasks, mock MRI, mock blood test, surveys), and the optional focus groups to provide more opportunities for feedback. The data collected allowed us to gain a comprehensive understanding of the acceptability of the protocol and areas for improvement. Another strength was the inclusion of participants from all four Orygen specialist clinics (EPPIC, HYPE, PACE, and YMC), as it allows our findings to be generalized to the broader population of young adults experiencing mental ill-health. Further, only one researcher conducted all the assessments, ensuring that the participant experience was identical for all participants.

Some limitations of the study include the small sample size and mock assessments, instead of real blood tests and MRIs. Another limitation is the extensive period between assessments (due to COVID-19 restrictions), which may have contributed to the lower follow-up and completion rates. Additional consideration is that assessment of acceptability was done by the same researcher who administered the protocol, which may have biased the responses in a positive direction.

The NYMHP protocol allows for the harmonization of data collection across research settings in the field of youth mental health. This can enable the production of large datasets, which hold important information about the clinical and neurobiological presentation of young people in the early stages of a mental illness. Large datasets could, for example, lead to the identification of biomarkers that can predict risk, outcome and treatment response (McGorry et al., 2014).

5 | CONCLUSION

This study tested the feasibility and acceptability of a harmonized data collection protocol in a sample of young people with various psychiatric diagnoses. Based on our observations, it appeared that the protocol is feasible and generally well-accepted by participants. The withdrawal rate and missing data were minimal, and the majority of subjective feedback from participants was positive. Most participants reported that it was not difficult to commit to the study and complete the assessments and agreed that they would participate again if given the opportunity. As a result, it is likely that the harmonization protocol will be accepted by young people in broader youth mental health research settings. The authors invite the reader to refer to the original publication (Lavoie et al., 2019) if they would like to use the protocol in their studies, taking the suggestion to reduce the length of the self-

reports into consideration. The wider implementation of this protocol would provide opportunities to create large datasets across youth mental health settings, allowing researchers to better understand how psychopathological and neurobiological changes occur in young people.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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