Medical Student Mental Health: A mixed methods and process mapping study

Research protocol (Version 1.0 22nd September 2022)

Research Governance Sponsor: The University of Sheffield
ScHARR REC number: 049592

Contents

Sheffield Clinical Trials Research Unit (CTRU)

Medical Student Mental Health: A mixed methods and process mapping study

Short title: MIND Study

This document describes a research study, and provides information about procedures for entering participants. The protocol is not intended for use as a guide to the treatment of other patients. Amendments may be necessary; these will be circulated to known participants in the study.

Abbreviations

AE	Adverse Event
BMA	British Medical Association
CCC	Confirmation of Capacity and Capability
CI	Chief Investigator
CRF	Case Report Form
CTA	Clinical Trials Assistant
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIS	Participant Information Sheet
PMG	Project Management Group
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SDV	Source Data Verification
SOP	Standard Operating Procedure
STH	Sheffield Teaching Hospital
SSI	Site Specific Information
TMF	Trial Master File

1. KEY CONTACTS

1.1 Investigator details

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1.3 Funder

This study is funded by the British Medical Association (BMA) Foundation. The views expressed are those of the author(s) and not necessarily those of the BMA. The funder has reviewed the research protocol but will have no role in data collection, analysis, data interpretation, report writing or in the decision to submit the report for publication.

1.4 Project Management Group (PMG) members

Name	Role	Institution
Elena Sheldon	Study Manager/ Research Associate (Chair)	School of Health and Related Research, The University of Sheffield
Christopher Burton	Co-Investigator	Academic Unit of Medical Education, The University of Sheffield
Daniel Hind	Professor of Evaluation, CTRU Lead	School of Health and Related Research, The University of Sheffield
Melanie Simmonds-Buckley	Clinical Psychology Lecturer and Researcher	Clinical and Applied Psychology Unit, The University of Sheffield
Jasmine Young	Medical Student	The Medical School, The University of Sheffield
Naseeb Ezaydi	Research Assistant	School of Health and Related Research, The University of Sheffield

1.5 Stakeholder Panel

Name	Role within study	Institution
Elena Sheldon	Study Manager/ Research Associate (Chair)	School of Health and Related Research, The University of Sheffield
Jasmine Young	Medical Student	The Medical School, The University of Sheffield
TBC	Medical Student	The Medical School, The University of Sheffield
TBC	Medical Student	The Medical School, The University of Sheffield
TBC	Medical Student	The Medical School, The University of Sheffield
Helen Crimlisk	Deputy Director	Sheffield Health and Social Care Foundation Trust
Charlotte Blewett	Consultant Psychiatrist	Sheffield Health and Social Care Foundation Trust
Fran Oldale	Director for EDI and Student Affairs and Support manager	The Medical School, The University of Sheffield
TBC	Professional Stakeholder	TBC
TBC	Professional Stakeholder	TBC
TBC	Professional Stakeholder	TBC

1.7 Protocol amendments

Version	Reason for amendment
1.1	Additional safeguarding procedure added to WP1 Added information about the handling of encrypted dictaphone devices, paper field notes and member checking as per ScHARR REC requirements

2. STUDY SUMMARY

Study Title:	Medical Student Mental Health: A mixed methods and process mapping study
Funder:	BMA Foundation
Grant start date:	1st September 2022
Project end date:	31st August 2023
Study design:	Mixed methods; process mapping
Setting:	The Medical School, The University of Sheffield
Participants:	Medical students
Inclusion criteria (see section 4.3.1)	1. Participant of any gender, aged 18 years old and over 2. Participants must be studying MBChB Medicine (A100) degree or the MBChB Graduate Entry Medicine (A101) degree at The Medical School, The University of Sheffield
Exclusion criteria (see section 4.3.2)	1. Participants aged below the age of 18 years 2. Participants who are not studying at The Medical School, The University of Sheffield 3. Significant language barriers, which are likely to affect the participant's understanding of the study, or the ability to complete outcome questionnaires 4. Participants who are unable to comply with the study protocol
Anticipated recruitment period:	1 year (September 2022 - August 2023)
Objectives (see section 3.2)	a) A cross-sectional online survey (CCAPS-34, demographic and service use questions) to characterise the population of at-risk medical students. b) A stakeholder panel of medical students and professionals stakeholders to co-design research materials and re-design support systems. c) Semi-structured interviews with a nested sample of medical students and professional stakeholders d) A co-designed process map based on multi-sector service pathways and determine where system failures may occur.

3. INTRODUCTION

3.1 Background

Overview: experience-based co-design to improve services
Mental health problems are prevalent among medical students(1–4), with a global prevalence of 27%(5). **Improved systems of support can only be achieved in partnership with their intended users**(6), participating on equal terms with other stakeholders, to define existing problems, develop and implement solutions and evaluate outcomes(7).

The proposed research will co-design a toolkit to enable student support services to better meet the specific needs of medical students. Medical students and health professionals will co-design research materials, interpret research data on unmet mental health needs and barriers to help-seeking. Finally, they will build on existing work to map multi-agency pathways for mental health support, as well as gaps in provision or access that affect medical students.

The general problem: poor mental health among medical students
The mental health of university students has become a major concern for higher education institutions (HEI) and policy makers(8). A meta-analysis of 183 studies across 43 countries showed that the prevalence of depression among medical students was 27.2%, with 11% of those students reporting suicidal ideation(9). Poor mental health among medical students is associated with adverse outcomes such as alcohol and substance abuse, self-harm and suicide attempts(10,11). A 2018 British Medical Association meeting reported that six UK medical students completed suicide in an 18-month period(12). This humanistic and economic burden makes research into how we can better meet the mental health needs of medical students an urgent priority.

3.2 Rationale for current study

Specific problem 1: identifying a representative range of at-risk medical students
In our systematic review(13), identifying as female, a history of mental illness, physical health problems, dissatisfaction with social life and academic stress consistently predicted depression, anxiety and psychological distress in medical students. The literature is, however, poor quality and heterogeneous, with a wide range of measures used to assess mental health outcomes(14). Collecting robust data using valid and reliable instruments that capture information about the unique context of HEIs is vital[14]. The Counselling Center Assessment of Psychological Symptoms (CCAPS-34**;** (15)) is a reliable, acceptable and psychometrically valid instrument for use in UK students(16–18). It includes HEI-specific psychological experiences, including items on academic distress, social anxiety and substance abuse. Collecting CCAPS-34 in conjunction with demographic and service use data will enable us to profile a student population, as well as to identify co-design partners and research participants.

Specific problem 2: understanding medical students' barriers to help-seeking
Responding to the mental health needs of medical students and ensuring that they receive the appropriate support to succeed at university is an urgent matter(18). Medical students

face particular sets of barriers to help-seeking and accessing mental health support, with less than a quarter of those with clinical levels of depression reporting using counselling services(19,20). Challenges to access include the stigma associated with mental illness, including stress, and perceiving a mental health problem as a form of weakness which may have implications for subsequent successful career progression(21). Reluctance to disclose mental health problems reflects medical students' beliefs about "fitness to practice" proceedings, the possibility of expulsion and reputational damage(20). Pressure from senior clinicians, distrust of medical school staff, social stigma and expectations about conduct are key concerns. The movement of student and NHS support services to internet-mediated provision during COVID-19 restrictions has resulted in additional challenges(22). Internationally, the barriers to help-seeking and accessing mental health support, which affect medical students disproportionately, are complex and multi-faceted(23–25). **There is however, a need for a more detailed and representative exploration of these barriers experienced by UK medical students, including overseas students**(18).

Specific problem 3: reconfiguring the system to meet the specific needs of medical students
HEIs have also seen a growing demand for services to meet the mental health needs of medical students(26,27). Student mental health services are required to provide brief in-house support to students, including counselling or mental health centres, disability and/or wellbeing services. Longer-term or specialist support for acute mental health problems are provided by external services. The Student Services Partnerships Evaluation and Quality Standards (SPEQS), developed by Sheffield and UCL, include a toolkit addressing challenges to cross-sector working from a professional perspective(28). **SPEQS provides generic groundwork that must now be tailored to the specific mental health needs of medical students.**

Access gaps, difficulty navigating pathways and resource constraints mean that medical students who do feel able to seek help can fall between the gaps(29). Students may delay approaching services until their needs are severe or impact their studies(17), and may turn to more acute care settings as a way of accessing the professional support they need(30). A U.S. study found that university students represented 8% (n=175) of attendances in a psychiatric emergency department over a one year period, with 27% of those students (n=46) admitted to the inpatient psychiatry unit(31). **Understanding the experiences of medical students who have 'fallen through the cracks' and the challenges to service provision are essential for overcoming barriers to access and improving the quality of existing services**(32).

4. AIMS AND OBJECTIVES

4.1 Aim

To capture the mental health profiles of medical students, understand their barriers to help-seeking or accessing support and the challenges of service provision, with a focus on medical students who have 'fallen through the cracks'.

4.2 Objectives

1) A cross-sectional online survey (CCAPS-34, demographic and service use questions) to characterise the population of at-risk medical students.
2) A stakeholder panel of medical students and professionals stakeholders to co-design research materials and re-design support systems.
3) Semi-structured interviews with a nested sample of medical students and professional stakeholders
4) A co-designed process map based on multi-sector service pathways and determine where system failures may occur.

The process map will build a visual model of support pathways, annotated with notes on system constraints and acceptability. A medical student-specific version of the SPEQS toolkit will be disseminated to medical schools to improve support service access and delivery.

5. PROJECT DESIGN

This is a sequential mixed methods study incorporating:

1. A cross-sectional online survey (Work package 1)
2. Convening a stakeholder panel (Work package 2)
3. Semi-structured interviews (Work package 3)
4. Co-design workshops with stakeholder groups (Work package 4)

Based on findings from the cross-sectional survey, a stakeholder group including medical students and professionals will be convened to design research materials for interviews and workshops for objectives 3 and 4.

6. WORK PACKAGE 1: CROSS-SECTIONAL SURVEY

This work package will conduct **a cross-sectional online survey to characterise the mental health profiles of medical students.** This section of the Protocol will be conducted in line with the preferred reporting items for cross-sectional studies (STROBE checklist, (33)).

6.1 Study design

As part of the mixed methods study, we will use a cross-sectional online survey (Qualtrics, Provo, UT, USA) comprising the CCAPS-34, with additional closed and open-ended questions on demographics, concerns, help-seeking behaviours, access, and service use, based on Broglia's work(18). Ethical approval will be sought from the University of Sheffield Research Ethics Committee.

6.2 Setting

We aim to recruit 165 medical students studying at The Medical School, The University of Sheffield. Recruitment will start in the first academic term of 2022, following the receipt of ethical approval.

6.3 Participants

6.3.1. Eligibility criteria

Inclusion criteria
In order to be eligible to take part, potential participants must meet all of the following inclusion criteria and must not meet any of the exclusion criteria.

A participant is eligible for the study if the following criteria are met:

1. Participant of any gender, aged 18 years old or over
2. Participants must be studying MBChB Medicine (A100) degree or the MBChB Graduate Entry Medicine (A101) degree at The Medical School, The University of Sheffield

Exclusion criteria
A participant is not eligible for the study if any of the following criteria are met:

1. Participants aged below the age of 18 years
2. Participants who are not studying at The Medical School, The University of Sheffield at the time of recruitment
3. Significant language barriers, which are likely to affect the participant's understanding of the study, or the ability to complete outcome questionnaires
4. Participants who are unable to comply with the study protocol

6.3.2. Sampling and Recruitment

All medical students who are studying at The Medical School, The University of Sheffield will be invited by email to take part in an online questionnaire study asking about their mental health symptoms, help-seeking behaviours and service use. The email will contain an anonymous web-link to the participant information sheet, the consent form and surveys. The web-link will remain open for seven days. The email will be circulated using the University's myAnnounce system during the first semester of academic year 2022-23. Participation is voluntary.

6.3.3. Informed Consent

The online survey will commence with an information sheet and informed consent page, to be read and completed prior to the questionnaires. In order for a participant to complete the questionnaires, all mandatory boxes indicating 'I consent' must be ticked. Following completion, the survey data with the consent fields will be downloaded as a CVS file by the research team at The University of Sheffield. Each participant will be automatically assigned an ID number via Qualtrics, the software which will be used to administer the online survey.

6.4. Variables

The online survey will comprise the CCAPS-34(15), with additional questions on demographics, concerns, help-seeking behaviours, access and service use.

The CCAPS-34 is a 34-item instrument with seven distinct sub-scales that are related to psychological symptoms and distress in university students. The seven CCAPS-34 subscales are:

1. Depression
2. Generalised Anxiety
3. Social Anxiety
4. Academic Distress
5. Eating Concerns
6. Frustration/Anger
7. Alcohol Use

Consent will be sought to collect demographic data, as follows:

1. Fee status (Home/birth country, International)
2. Year of study (Years 1-5)
3. Gender (Female, Male, Non-Binary, Rather not specify)
4. Ethnicity (White, Asian or Asian British, Black African or Black Caribbean, Mixed/Multiple ethnic groups, Other ethnic group, Rather not specify)

Questions on mental health concerns, help-seeking behaviours, service access and use will include:

1. Have you *previously* received mental health support before you started studying medicine at The University of Sheffield?
   Yes / No
2. Have you *previously* received mental health support from The University of Sheffield's counselling, NHS services* and/or a psychological wellbeing service whilst studying at University?
   Yes / No
3. Are you *currently* receiving support from The University of Sheffield's counselling, NHS services* and/or psychological wellbeing service?
   Yes / No
4. Have you ever had concerns about your mental health and decided *not* to seek help from The University of Sheffield's counselling, NHS services* and/or other psychological wellbeing services?
   Yes / No

*Examples of services may include, but are not limited to, your GP, Sheffield IAPT, Single Point of Access (SPA)

Responses will be multiple choice but where participants indicate 'Yes' an open-ended free text box will prompt for further elaboration of students' concerns and reasons for seeking or avoiding help.

6.5. Data sources and outcome measurement

The CCAPS-34 is a shorter version of the CCAPS-62 and both are typically used in university counselling services to assess student-specific psychological experiences. In this context the measure will be used to assess psychological experiences specific to the medical student population. Permissions will be sought from the developers to include the CCAPS-34 in the online survey; no changes will be made to the measure. Items refer to the previous two weeks and are rated on a 5-point Likert scale (0 = not at all like me, 4 = extremely like me) where higher scores indicate higher severity. It takes approximately 2-3 minutes to complete.

At the end of the survey, participants will be shown the following text as per the Participant Information Sheet:
If you have concerns after completing this survey we suggest seeking help from any one or more of the following sources of support and advice:

- Your GP;
- The Samaritans (**tel:** 116 123; **email:** jo@samaritans.org)

- Sheffield Nightline - if you would like to talk to one of the Sheffield Nightline volunteers over the phone, phone lines are open from **8pm – 8am every day apart from Wednesday and Saturday during term time**. You can reach them through the number below (we are also on the back of your UCard if you forget!)

tel: 0114 222 8787**; email:** listening@sheffield.nightline.ac.uk

- NHS 111 for urgent medical advice

If you'd like to receive further mental health support the Student Access to Mental Health Support (SAMHS) at the University of Sheffield is the first point of contact for you to explore a broad range of mental health support needs in a single triage appointment. Through a triage appointment, you can access a wider number of options that will be recommend to support your mental health. To book an appointment with SAMHS, go to: https://www.sheffield.ac.uk/health-service/conditions/mental-health (student login required).

6.6 Sample size

Based on 2021-22 enrolment figures, the email will be sent to an estimated number of 1,500 students (5-year programme, 300 students per year). Online surveys have no agreed-upon minimally acceptable response rate(34,35), but the average is 11%(36) and representativeness of response is thought to be more important(37). The target sample size is estimated at 165 medical students.

6.7 Quantitative variables

Items are rated on a 5-point Likert scale (0 = not at all like me, 4 = extremely like me) with higher scores indicating higher severity.

Each subscale of the CCAPS has two interpretive thresholds, or cut-scores, which are used to facilitation the interpretation of responses. The thresholds divide each subscale into three ranges of distress: Low, Moderate, and High (16). Low scores are consistent with university students who report no, or minimal, distress in each area. Moderate scores in this range are most consistent with university students who report moderate distress in each area, and further assessment is recommended to determine the nature of the distress. High scores are described as “elevated” and are consistent with high levels of distress that should be further assessed for a diagnosis if the subscale is associated with a diagnostic area (i.e. Depression, Social Anxiety, Eating Concerns, etc.).

6.8 Statistical methods and analysis

Online survey data will be analysed descriptively and using mixed factorial ANOVAs and post hoc simple effect analyses to characterise the mental health profiles of medical students.

For responses to the additional closed and open-ended survey questions, we will use the five stages of National Centre for Social Research’s ‘Framework’ analysis(38) within NVivo (QSR international, London, UK): familiarisation; identifying themes; indexing, charting; interpretation/mapping. Joint display tables will integrate interview and survey data to understand students’ mental health concerns and barriers to help-seeking and challenges for service access and delivery. Findings of WP 1 will inform the design of WP2 and both work packages will inform WP4.

7. WORK PACKAGE 2: CONVENING A STAKEHOLDER PANEL

Co-production aims to define the problem, develop and implement interventions and evaluate outcomes in partnership with patients, researchers, care professionals and other relevant stakeholders(7). Co-design will follow four phases(39):

1. Set up a core group of stakeholders, including medical students and professionals (WP2)
2. Discovery phase (WP3): interviews with stakeholders to identify touchpoints
3. Co-design phases (WP4): Several quality improvement groups working with students and professionals to prioritise touchpoints and design activities to target touchpoints
4. A closing event with all those involved to celebrate the gains

To meet the second objective, we will convene a stakeholder panel of medical students and professionals. Medical students will be purposively selected based on their responses to the online questionnaire. Professional stakeholders will be approached based on their role and institution, ensuring representation across university and external support services. Stakeholders will be approached about the study by email. The stakeholder panel will co-design research materials and re-design support systems.

8. WORK PACKAGE 3: SEMI-STRUCTURED INTERVIEWS

To meet the third objective, **semi-structured qualitative interviews will be conducted with medical students (n=20) and professional stakeholders (n=10).** Challenges to service access and provision including system constraints, resource limitations and inter-agency working will be explored. Interview findings will show the unmet needs of students and staff in terms of service accessibility, acceptability and delivery. This section of the Protocol will be conducted in line with the preferred reporting items for qualitative research with interviews and focus groups (COREQ checklist, (40)).

8.1 Design

Semi-structured qualitative interviews with participants should be considered as a key part of the mixed methods study.

8.2 Theoretical framework

Interview guides will be developed informed by Biddle and Rickwood's theories of (non-) help-seeking in young adults(41), covering known barriers to help-seeking(18), known risk factors(13) and the SPEQS toolkit(28). See section 8.6.1.

8.3 Participant selection

Based on the online questionnaire data (WP1), a sub-sample of 20 medical students will be selected for interviews and invited to take part by email. We will sample for maximum variation based on self-reported symptoms and help-seeking experiences and known risk factors(13), or those facing particular barriers to help-seeking, such as international students. Ten professional stakeholders including health professionals, university staff and service managers working in university or external healthcare settings will be invited to take part by email. This may include, but is not limited to, psychiatrists, psychologists, specialist nurses, counsellors and advisors, service managers and general practitioners. This should be adequate for data saturation(42).

8.4 Setting

The interviewer will collect data face-to-face, by telephone or Google Meet, a secure video-communication service, depending on participant preference. Interviews will be conducted between January 2022 and August 2023 by trained ScHARR researchers with qualitative research experience.

8.5 Informed Consent

Informed consent will be obtained from every participant. Interviews will be scheduled at a time convenient for participants by one of the study team who will read the information sheet through with them. If the participant is happy to continue the study team member will complete the consent form by telephone or in-person before the interview. Telephone consents will be recorded on encrypted digital recorders. Those involved in taking consent and collecting data will have up-to-date training in Good Clinical Practice (GCP). Participants

will be reassured that all data which are collected during the course of the research will be kept strictly confidential. Participants will be allocated a unique identifier (such as P01, P02, and so on) to maintain confidentiality. All personal information such as Names and Place Names will be removed from the transcripts during the transcribing process. Spontaneously offered reasons for non-participation will be recorded. The consent form will be completed prior to data collection, and approved by The University of Sheffield's Research Ethics Committee.

8.6. Data collection

8.6.1. Interview guides
The interview guides will be developed in consultation with the stakeholder panel, including health professionals, researchers and medical students with lived experience of mental health problems. For professional interviews, their background and role in delivering mental health care will be collected. Medical student participants will be asked for their gender, age, ethnicity, year of study and (if applicable) their mental health diagnosis. Topic guides will also be based on findings from WP1 and supporting literature and will be submitted to the ethics committee as an amendment for approval.

8.6.2. Recording
Encrypted digital recorders will be used and recordings will be uploaded to a secure X:Drive folder by the researcher for transcribing and analysis. Once saved, recordings will be permanently deleted from the digital recorder. All interviews will be fully transcribed. At the end of the study audio recordings will be destroyed.

8.6.3. Field notes
Field notes will be taken during and after interviews as required. Field notes will not include identifiable information. Field notes taken during and after interviews will be typed in a word document and stored securely on the X:Drive. Any handwritten notes will be typed after the interview and stored on the X:Drive folder, with the paper copy shredded (and therefore destroyed).

8.6.4. Duration
Interviews will last up to one hour. Transcripts will be returned to participants for clarification where the recording is indistinct or unclear.

8.6.5. Safety of the participants
We do not consider the healthcare professionals to be vulnerable participants in this instance. Interviews will be treated as confidential; information that identifies individuals such as name or date of birth will not be disclosed. The Participant Information Sheet includes contact details and information for information for contacting support services such as Student Access to Mental Health Support (SAMHS), The Samaritans and Sheffield Nightline.

8.6.6. Member Checking
Member checking will be undertaken to ensure that our interpretation of an interview accurately reflects the participants' intended meaning. Researchers will ask at the end of the

interview if the interviewee is happy to be contacted for this checking process, which is also detailed in the information sheet. After analysis we will contact the participant by email. A summary of what was understood will be related to the participant and followed up with the questions, “have I understood correctly what you wanted me to know?” and "is there anything else that should be in there?". Participants will only be asked to member check their own interview transcript which will be anonymised (all direct identifiers removed) and password protected before sending via email. The password will be emailed to the participant separately. This detail has been added to the Protocol and ethics application.

8.7. Data analysis

We will use the five stages of National Centre for Social Research’s ‘Framework’ analysis(38) within NVivo (QSR international, London, UK): familiarisation; identifying themes; indexing, charting; interpretation/mapping. Joint display tables will integrate interview and survey data to understand students’ mental health concerns and barriers to help-seeking and challenges for service access and delivery. Findings will inform WP4.

9. WORK PACKAGE 4: CO-DESIGNED MULTI-SECTOR ‘PROCESS AND BARRIERS’ MAP

To meet the fourth objective, we will deliver a series of **co-design workshops** with stakeholders to create **a process map based on multi-sector service pathways and determine where system failures may occur.**

9.1 Background

Two to three co-design workshops will involve process mapping. Process maps define: 1) *what* support services do; 2) *when* services are accessed and in what order; 3) *where* services are accessed; and 4) *who* is responsible for service delivery(43). When a process is well understood, maps can be used to identify service gaps and opportunities for improvement, engage key stakeholders, learn collaboratively and produce a tangible output - the process map(44). Due to the complexity of student support services, and how universities interact with external services, process mapping will be used to visualise a step by step flow of the student journey. Tasks, goals, constraints, resources and actors, as well as the emotional and physical aspects of accessing mental health support, will be reviewed to identify gaps in service access and delivery.

9.2. Methodological orientation and theory

Based on the methodological literature presented in Antonacci’s 2021 systematic review(45) of process mapping in healthcare, the following five phases will be followed

9.2.1. Preparation, planning and process identification

Professionals and medical students will be identified from the stakeholder panel and asked to take part in a series of process mapping workshops. Workshops will not be recorded. Stakeholders attending the workshops are not research participants but experts by profession or by experience; informed consent will therefore not be required. An opt-out form will be filled out by members of the stakeholder panel who do not wish to take part in the work packages. Training will be provided to stakeholders to fill skills gaps, if needed. For example, process mapping exercises may include a quick introduction to the method and show examples from the literature.

9.2.2. Data and information gathering

Information will be gathered by the Project Manager to inform the process mapping exercises. Data may be collected from: Project Management Group meetings; the stakeholder panel; findings from the cross-sectional survey and qualitative interviews and other relevant literature or document analysis.

9.2.3. Process mapping generation

Different perspectives from professionals and medical students will be gathered by people having diverse roles and lived experiences, each brining their view and knowledge of the process under analysis.

9.2.4. Analysis

The process map will be analysis to identify gaps in the systems and opportunities for improving the mental health support and services provided to medical students. The final process map will be checked for accuracy and validated by key stakeholders and experts. During the analysis phase the process map will be annotated with information derived from the analysis (e.g. activity durations, resources involved) and transfer paper-based maps in an electronic format (using the aforementioned software tool). Having a tidy electronic version of the process map supports the analysis and documentation of the exercise and is useful for disseminating to interested parties or those involved in the process for comments and validation.

The process map will respond to and incorporate information on cross-sector working, provision, access and help-seeking behaviours identified in WP1 and WP3. Recommendations for improvements to individual services and cross-sector working, will be made with reference to the SPEQS framework(46) and domains of mental health service quality (Table 1)(47). Da

Table 1. Key performance indicators of high-quality mental health care

Performance indicator	**Example metric for measurement**
Clinical safety	How risk is assessed and mitigated at service entry

Accessibility	Ease of access for high risk sub-populations of students
Effectiveness	Proportion of users with improved mental health outcomes
Acceptability and satisfaction	Student satisfaction with care
Efficiency	Cost-effectiveness of care
Appropriateness	Matching service provision to clinical stage, which is an adjunct to mental health diagnosis that incorporates illness severity and risk of progression to facilitate appropriate treatment matching
Continuity and coordination	Successful transitions between services, e.g. from university to external services or between primary and secondary care
Workforce competence and capability	Assignment of skilled staff to specific interventions

9.2.5. Taking it forward

The process maps will be used to guide process improvement initiatives. Improvement ideas and actions generated through the process mapping exercise will be implemented to improve current systems and practice. We will co-produce a toolkit to guide services to meet the specific mental health needs of medical students, disseminating it to: the Student Access to Mental Health Support (SAMHS) service at the University of Sheffield and their counterparts at every UK University; local NHS organisation; the Student Mental Health Research Network (SMaRteN, https://www.smarten.org.uk/); the GMC; The Academy of Medical Educators; and, The Association for the Study of Medical Education. Manuscripts will be submitted to peer review journals. Conference and CPD presentations will be given.

9.2 Subjects

Student and professional stakeholders will be invited to take part in a series of co-design workshops. We will aim to recruit 6-12 workshop participants, ensuring representation of the different stakeholder categories and medical student profiles (year of study, mental health profiles, demographics, help-seeking behaviours and experiences of support services).

9.3. Tools for Process Mapping

A visual management software tool such as Microsoft Visio will be used for creating flow charts. A variety of flow chart symbols are used to represent different types of activities. The most commonly used symbols and shapes are the box, diamonds, arrow and oval(48). *Boxes* represent an activity step in the process flow. The process step is described briefly within the box and identifies the person, function or organisation responsible for that step. *Diamonds* show decision steps and are tied to a question (for example, 'Is the criteria for

admission met?'). Based on the answer (e.g. Yes/No) a different pathway will be followed. *Arrows* point the direction of the process flow from one symbol to the next. *Ovals* represent the beginning or end of the process.

10. DATA MANAGEMENT AND RECORD KEEPING

10.1 Data collection

Responses to the cross-sectional survey will be stored and processed using services provided by Qualtrics. These services have been the subject of independent assessment to ensure compliance with applicable data security standards. Further information can be found on the Qualtrics website (https://www.qualtrics.com/security-statement/). Responses will be downloaded as a CSV file and saved as an Excel file on the secure University of Sheffield X: Drive, in line with University procedures.

The recordings of the semis-structured interviews taken from Google meet or the encrypted Dictaphone recordings will be stored on the secure University of Sheffield X: Drive, in line with University procedures. Once returned from the ScHARR transcription service, interview transcripts will be stored in the University of Sheffield X: Drive.

Only where survey participants from WP1 put themselves forward to participate in an interview or stakeholder panel will volunteer their name and email address. This information will be kept on encrypted University of Sheffield desktop or laptop machines before being uploaded to a password-protected area of a University secure server with access restricted to authorised members of the research team. The information may be used to contact individuals to arrange an interview or stakeholder panel meetings.

Quotations from the interview and basic demographic information from the survey – but no other personal data – will be shared, with verbal consent, by the researcher, with the members of the wider research team. For students, basic demographic data will involve: fee status; Year of Study; Gender; and Ethnicity. For professionals, it will involve Occupation only. Any direct quotes from the interviews used in publications will be anonymous. The Participant Information Sheets and consent forms make this clear to patients before consent. Participants are informed at enrolment that access to records we hold may be required by the CTRU (University of Sheffield) and regulatory authorities for the purpose of monitoring where it is relevant to their participation in the research.

10.2 Data confidentiality

Participant confidentiality will be respected and maintained at all times and the principles of the UK General Data Protection Regulation (GDPR) will be followed. The investigators will ensure that identifiable data is kept securely and protected from unauthorised parties.

All participants will be assigned a unique study ID number prior to consent that will link all of the clinical information collected for them. Study documents (paper or electronic) will be retained in a secure location during and after the trial.

Any data held by the CTRU will be stored in accordance with the archiving Standard Operating Procedure (CTRU SOP PM012) for 10 years following completion. Archived documents will be logged on a register which will also record items retrieved, which will be done by named individuals, from the archive. Electronic data will be stored in an 'archive' area of the secure CTRU server for a minimum of 10 years to ensure that access is future-proofed against changes in technology. Electronic data may also be stored (e.g. on a compact disc or USB flash drive) with the paper files.

11. DATA ACCESS AND QUALITY ASSURANCE

A risk assessment has been performed by the CTRU, in accordance with Sheffield CTRU Standard Operating Procedures in preparation for study setup and ethical review. The risk assessment will be periodically reviewed throughout the project to identify and mitigate any potential study risks.

The survey responses and semi-structured interview data will be stored on the University X: Drive. Only the University of Sheffield project team (Elena Sheldon, Naseeb Ezaydi, Daniel Hind, Christopher Burton) will be able to access the project data.

12. MONITORING AND OVERSIGHT

12.1. Management of the study

A Data Monitoring and Ethics Committee will not be convened in this study due to the low risk nature.

The project is led and organised by the University of Sheffield as the grant holder. The Project Management Group (PMG, membership listed on page 7), will govern the conduct of the study on a day to day basis. The Study Manager will be jointly supervised by the CTRU Lead and members of the PMG via the form of regular meetings (video conference calls). The Study Manager will be responsible for liaising with the whole project team.

A stakeholder panel (listed on page 8) will provide direction and governance throughout. The aim of the panel is to guide and govern the PMG, ensuring that the work is adhering to the project objectives and plan, and is ultimately driven by delivering benefits to medical student mental health. It will be the responsibility of the Study Manager to adhere to the project budget, and will report to the CTRU Finance Team, PMG and Funder.

12.2. Harms

It is not anticipated that there will be SAEs related to the collection of survey or interview data.

13. PUBLICATION AND DISSEMINATION

Results of the study will be disseminated through peer-reviewed scientific journals, a manuscript of which will be sent to the funder.

We will co-produce a toolkit to guide services to meet the specific mental health needs of medical students, disseminating it to: the Student Access to Mental Health Support (SAMHS) service at the University of Sheffield and their counterparts at every UK University; local NHS organisation; the Student Mental Health Research Network (SMaRteN, https://www.smarten.org.uk/); the GMC; The Academy of Medical Educators; and, The Association for the Study of Medical Education. Manuscripts will be submitted to peer review journals. Conference and CPD presentations will be given.

Details of the study will also be made available on the Sheffield CTRU website. Summaries of the research will be updated periodically to inform readers of ongoing progress.

14. FUNDER

The MIND study is funded by the British Medical Association (BMA).

14. ETHICS APPROVAL AND REGULATORY COMPLIANCE

14.1 Approvals

Before initiation of the study, the protocol, informed consent forms and information materials to be given to the participants will be submitted to the ScHARR Research Ethics Committee. Any further amendments will be submitted and approved by the ethics committee. The project will be conducted in accordance with Good Clinical Practice (GCP) Guidelines and CTRU standard operational procedures.

14.2 Declaration of Interests

There are no interests to declare.

15. INDEMNITY / COMPENSATION / INSURANCE

The University of Sheffield has in place clinical trials insurance against liabilities for which it may be legally liable, and this cover includes any such liabilities arising out of this study.

As the Sponsor is an NHS Trust, indemnity is provided through NHS schemes in respective of the Governance for the overall project. The following risks will be overseen by a Patient Oversight Committee chaired by Crohn's & Colitis UK and a Project Leadership Group chaired by Professor Alan Lobo, Sheffield NHS Trust.

The Sponsor will enter into a Service Level Agreement with VoiceAbility to ensure service provision and the corresponding financial budget schedule are reviewed and approved by both parties.

Key risks related to finance/indemnity, contracting, site staff, recruitment and withdrawal, data, site file maintenance, study implementation, external organisations, protocol compliance and COVID-19 are addressed fully in the risk register.

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