

Developing an occupational therapy intervention to improve mental well being among young people.

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Registration date 27/02/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/09/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A growth in the prevalence of mental illness and poor mental 'wellbeing' in young people has increased concern internationally. The development of early interventions to reduce the impact of illness, associated financial and social burden is now a research priority. The early stages of mental illness typically begin in adolescence and are established by 24 years of age in 75% of cases.

Adolescence is widely considered a critical period for neurological, biological and psycho-social development associated with transitioning into adult roles. Biographical disruption such as mental illness, during this period can have significant lifelong implications and disrupt everyday occupations. Occupational engagement and participation, is understood as all activity in which an individual engages or participates in, also changes during adolescence as they begin the creative process of exploring and working towards developing competency in adult roles.

Occupational Therapy is a unique approach that views engagement and participation in meaningful occupation (activity) as central to achieving health and wellbeing. The approach applies knowledge and understanding of occupation as a therapeutic intervention enabling people to achieve an occupationally balanced and meaningful life, consequently effecting their experience of health and wellbeing.

Underpinned by the Intervention Mapping approach, this research study utilises a multi-phase mixed method feasibility design to develop an occupational therapy intervention for young people experiencing early stages of mental health problems.

The initial phases of the study focus on developing and consolidating Occupational Therapy theory through the exploration of adolescent perceptions and experiences of engagement and participation in meaningful occupation. This newly generated knowledge will be used in conjunction with existing knowledge and theory from a systematic scoping review to develop an intervention manual. The final part of the study is to test the feasibility of the manual and identify the practical issues related to its use.

Who can participate?

Two or three mainstream schools will be invited to participate in the study. They will be informed of what the research involves and will be required to formally agree to the research protocol. All lower 6th form students (Aged 16 to 17 years) from each of the participating schools will be invited to participate in the study.

What does the study involve?

Phase 1, involves the delivery of a presentation about the study and information about participating during non-class time. Participants are then given an information leaflet and invitation to take away. On a second occasion a further presentation is given explaining how to complete two questionnaires should they decide they want to take part. Those not taking part are provided with an informative article about research methods.

Those taking part will be required to complete a consent form and provided with a Strengths and Difficulties questionnaire (SDQ), basic demographic questions and a 24 Time Use diary. They will be asked to complete the SDQ for how they feel now and the 24 hour time use for the last 24 hours. They are also given a time use diary to take away and complete over the weekend, to be returned to school once completed.

Phase 2, A stratified sample from study 1 will be invited to take part in phase 2. Participants will have indicated in phase 1 that they would be willing to take part in phase 2. Participants will be invited to participate in a small focus group. Focus group participants will be asked to complete a warm up activity using the Activity Card Sort for Adolescents and Young Adults (ACS-AYA) the group will then be asked specific questions about occupation. The focus group verbatim transcripts will be analysed using grounded theory.

Phase 3, Involves a systematic scoping review of the literature in relation to Adolescents, Occupation and mental health interventions. The protocol for which will be published separately.

Intervention Manual development. This will be developed using the information from the first 3 phases of the study. The manual will be reviewed and piloted by Occupational Therapists working in the field and others with appropriate back ground in the field, prior to phase 4.

Phase 4, focuses on feasibility testing. A School test site(s) will be identified. N. 16 to 50 adolescent Lower 6th form students will be identified to be participants. They will be invited to a meeting with the researcher to explain the research and gain consent. They will then be asked to complete a Children's Occupational Self-assessment form (COSAS), the SDQ and a time use diary. They will then be assigned to either the control group or treatment group. All Participants will be asked to complete the questionnaires again at mid-point and at the end point. In addition to this they will also be asked about their experience of participating in the group. The treatment group will be led by an occupational therapist trained in use of the manual and how to run the group. The facilitators of both the treatment and the control will be asked to keep a weekly record of their experience of running their respective groups. Quantitative and qualitative data will be analysed to test feasibility of implementation and delivery and potential benefit in order to inform iterative development for a follow-on trial.

What are the possible benefits and risks of participating?

Benefits:

1. The study provides those who take part an opportunity to learn about research process.
2. The study hopes to develop an intervention that will help those struggling with mental health difficulties.

Risks:

1. Every effort is made to minimise the risks of this project. There is a possibility that some will find this topic difficult because of their own or other experiences of mental health. Safeguards are built in at every stage of the research design including: suitability checks with teaching staff, information and advice on where support and help can be accessed, a procedure for dealing with a safeguarding disclosure and appropriately qualified staff leading the various parts of project.
2. The project will also be subject to scrutiny by the Oxford Brookes University Research Ethics board.

Where is the study run from?

The research team is based at Oxford Brookes University and the study itself will be run in participating schools.

When is the study starting and how long is it expected to run for?

September 2017 to December 2022

(updated 23/11/2020, previously: The study start date is March 2018 and is expected to run till July 2020.)

Who is funding the study?

The study is being funded as part of a PhD studentship sponsored by the Elizabeth Casson Trust (charity) and academically supported by Oxford Brookes University.

Who is the main contact?

Jackie Parsonage

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

PROTOCOL 1 2017

Study information

Scientific Title

Developing an occupational therapy theory based intervention to improve mental well being for young people: a mixed method study

Acronym

AFI

Study objectives

The study is divided in to 4 parts the following aims and objectives, relate to the study as a whole.

Aim 1:

To identify and describe current levels of occupational engagement, participation and emotional wellbeing, in an adolescent school cohort.

Objectives:

1. To describe occupational engagement in a stratified purposive sample of the adolescent population.
2. To explore the extent of the relationship of occupational engagement and participation to emotional wellbeing across a stratified purposive sample of adolescents.

Aim 2:

To explore 'occupational choice' and perceptions of emotional wellbeing in a current adolescent cohort.

Objectives:

1. To explore adolescent perspectives of engaging and participating in currently meaningful occupations and how they impact perceptions of mental and emotional wellbeing.
2. To compare and contrast the perspectives and perceptions from different purposively stratified groups.

Aim 3:

To develop and test the feasibility of a manualised Occupational Therapy theory based intervention designed for use with adolescents with emerging mental health issues.

Objectives:

1. To conduct a theory-based literature review to determine appropriate theories to inform the logic model development of an occupational therapy intervention manual for adolescents with emerging mental health issues.
2. To develop an occupational therapy theory-based manual for adolescents with emerging mental health issues.
3. To conduct initial feasibility testing of the manual in concordance with current good practice guidelines for complex interventions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study 1 & 2: Approved 19/04/2018, Oxford Brookes University Research Ethics Committee (Oxford Brookes, Oxford Institute of Nursing, Midwifery and Allied Health Research (OxINMAHR), Oxford Brookes University, Gipsy Lane, Oxford, OX3 0BP; Email: ethics@brookes.ac.uk), ref. UREC 181192

Study 3 is a literature review that does not require ethical approval

Study 4: not provided at time of registration

Study design

A multi-phase, mixed method feasibility study

Study 1: observational, cross sectional cohort using questionnaires.

Study 2: focus group design using a cross sectional stratified sample and a grounded theory approach.

Study 3: systematic scoping review

Study 4: initial feasibility testing of a 6-8 week intervention with identified client group.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mental health and well being

Interventions

The overall study utilises the Intervention Mapping Model as a frame work for a multi-phase, mixed method feasibility design which adopts a pragmatic approach.

Phase 1: Quantitative survey method of A school cohort sample of 16/17 year olds given 2 questionnaires to complete. One a Strengths and difficulties questionnaire and the other a Time Use diary. Analysis will primarily be descriptive but some inferential statistics may be used.

Phase 2: Qualitative Focus Groups using a grounded theory methodology will be used. The sample will be taken from a purposive stratified sample from study 1. A semi structured topic guide will be used to structure the discussion.

Phase 3: A literature review to be completed using a systematic Scoping review method.

Phase 4: This Quant/Qual study is still in the development phase as it is dependent on earlier stages of the study. It involves manual development in partnership with other professionals in the field, Initial piloting and then initial feasibility testing of the manual. Approximately 15 to 50 students will be recruited to the study and assigned at random to either a control group or the intervention group. The control and treatment groups will last between 1 and 2 hours over a maximum of 9 weeks. Assessments will be conducted at baseline, mid-point and at the end of the groups. Feedback will also be sort from participants and those leading the groups. Therapists will be given training in use of the manual prior to the start of the intervention.

Intervention Type

Behavioural

Primary outcome(s)

'Occupation' will be measured using Time Use diaries, and the Children's Occupational Self-assessment tool (COSA) at Baseline, mid intervention point and the end of the intervention.

Key secondary outcome(s)

1. 'Mood and Behaviour' will be measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, mid intervention and at the end of the intervention.
2. 'User experience' will be measured using feedback from participants and intervention facilitators at the end of the intervention.

Completion date

31/12/2022

Eligibility

Key inclusion criteria

Study 1 & 2 : Consenting year 12 A level student cohort in identified schools.

Study 4: young people with emerging mental health difficulties. (Inclusion criteria to be further defined at a latter date.

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

Study 1: Those who refuse to provide consent.

Study 2: Those for whom it is identified that participating in a focus group is not in their best interest following initial prep meeting.

Study 4: Those not consenting on not well enough to participate and those not meeting the criteria yet to be identified.

Date of first enrolment

01/10/2018

Date of final enrolment

31/12/2021

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Centre for Movement, Occupation and Rehabilitation Sciences (MORes)

Oxford Institute of Nursing, Midwifery and Allied Health Research (OxINMAHR)

Oxford Brookes University, Gipsy Lane

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Sponsor information

Organisation

Oxford Brookes University

ROR

<https://ror.org/04v2twj65>

Funder(s)

Funder type

Charity

Funder Name

Elizabeth Casson Trust

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	A Delphi method investigation to prioritize activity-related determinants thought to affect mental health in adolescent populations	08/02/2024	25/09/2024	Yes	No

Results article	An exploration of occupational choices in adolescence: A constructivist grounded theory study	09/11/2020	25/09/2024	Yes	No
Other publications	Scoping review	29/06/2022	25/09/2024	Yes	No