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Optimising the management of mental health problems in primary care

Submission date	Recruitment status	[X] Prospectively registered
13/01/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/01/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/02/2021	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression and anxiety are common problems and a major cause of disability in the UK. Most people with these conditions are managed in primary care and will be offered a variety of options depending on the severity of symptoms, local service availability and personal preference.
This study will evaluate the effectiveness of a new treatment pathway designed to optimise the patient experience without increasing the cost burden. It uses new technologies to help patients identify and engage with support, manage symptoms and monitor response.

Who can participate?
Patients aged 18 years or older who attend the nurse-led mental health clinic at the trial centre.

What does the study involve?
Participants who are eligible and agree to take part will have their details registered on the I-spero system which will assist the clinician in identifying the most appropriate management option for their condition. Treatment will continue as usual for eight weeks, at which time participants will be asked to complete a satisfaction questionnaire.

What are the possible benefits and risks of participating?
Benefits include the chance to use new technology before widely available. No risks.

Where is the study run from?
The University of Nottingham Health Service, UK

When is the study starting and how long is it expected to run for?
January 2020 to August 2020 (updated 24/02/2021, previously: June 2020)

Who is funding the study?
1. The Microcurrent Site Limited, UK
2. P1vital Products Limited, UK
3. National Institute for Health Research (NIHR), UK

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271778

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44191, IRAS 271778

Study information

Scientific Title
Optimising the effectiveness of the management of mental health problems in primary care using new technologies

Study objectives
The optimised pathway improves the management of mental health problems in primary care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2019, NHS Wales REC 6, (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; +44 (0)1874 615949; Wales.REC6@wales.nhs.uk), ref: 19/WA/0344

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mood [affective] disorders, Neurotic, stress-related and somatoform disorders

Interventions
Entry into the study will be offered to attendees at a nurse-led clinic for people who have mental health problems which will be set up in Nottingham, UK. The clinic will run at the student health centre on the University of Nottingham main campus. All attendees will be assessed by a trained mental health nurse on presentation to the service. Those eligible to participate must be registered with the practice, must be aged 18 or over, must have capacity to understand the patient information sheet and give consent to participation and must not require immediate referral to secondary care because of symptom severity. Patients not meeting these criteria will be offered usual care according to the standard operating procedures of the service. Patients who are eligible to join the study will be given an information sheet and time to consider participation. Those who do not give consent will be offered usual care according to the standard operating procedures of the service. Those who consent will be entered into the trial.

The first study procedure will be registration with the ispero system (CE-marked but not currently part of standard management) and completion of the baseline assessments it contains. The results of this will be available immediately and will assist the clinician in identifying the most appropriate management option. This could be one or more of the following:
- self help
- support agencies including NHS, University and voluntary sector
- psychological therapy with one of the three NHS provider organisations in Nottingham
- Alpha-Stim treatment for those with generalized anxiety (CE-marked but not currently standard management)
- referral to a GP to discuss medication

The participants' response to these options will be monitored by ispero and used at future contacts to guide further management.

There will be no planned study visits but participants will be seen by the appropriate clinician at intervals agreed at the end of each contact.

Eight weeks after recruitment an investigator will contact the participant and ask permission to inspect their I-spero data and collect outcome measures. They will be offered an opportunity to withdraw consent for participation at this point. They will also be offered a personal appointment with a study clinician so that data can be reviewed in a consultation environment. They will also be asked to complete a short satisfaction survey.

A control group of patients attending their GP practice with mental health problems that would have been eligible for inclusion in the study will be identified at the end of the study and a retrospective notes review will be performed by the investigator as part of routine service evaluation. It will be possible to compare some of the baseline and eight week outcome measures as this information is collected as part of standard practice.

Any data extracted for comparison will be fully anonymised and no patient identifiable data will be seen by any person who is not an employee of the study practice.

The null hypothesis will be that the new pathway is no more effective or acceptable than standard treatment. This design has been chosen as it aligns with current NHS priorities and causes minimal disruption to participants and local services. We considered a randomised controlled design but felt that this would cause ethical and logistical problems that would not outweigh the benefits in outcome data quality and comparability.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Alpha-Stim

Primary outcome measure
Improvements from baseline to 8-weeks in I-spero data (I-spero uses a number of validated tests and an AI algorithm to monitor response to treatment)

Secondary outcome measures
Satisfaction as measured by questionnaire at 8 weeks

Overall study start date
01/08/2019

Completion date
01/08/2020

Eligibility

Key inclusion criteria
1. Attendance at nurse-led mental health clinic
2. Registered with participating general practice (this is necessary to ensure that clinical alerts generated by the ispero system can be acted upon in a timely manner)
3. Capacity to understand information sheet and provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
55

Key exclusion criteria
1. Patients not suitable for the nurse-led mental health clinic. These would include those who appear distressed or at acute risk of harm to themselves or others or who appear to be intoxicated. The reception staff at the practice are already skilled in identifying these patients. The nurse-led clinic would also not be suitable for those with mental health problems related to a terminal or acute physical illness.
2. Those unable to communicate effectively in English

Date of first enrolment
01/02/2020

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Nottingham Health Service
Cripps Health Centre
University Park
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Sponsor information

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University of Nottingham

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Sponsor type
University/education

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Sponsor type
Industry

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
The Microcurrent Site Limited

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
P1 Vital Products Limited

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No