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StratCare Trial

Submission date	Recruitment status	[X] Prospectively registered
25/07/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/07/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/08/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Patients with depression and anxiety problems accessing the English National Health Service are commonly referred for psychological treatment in IAPT services (Improving Access to Psychological Therapies). IAPT services organise treatment in a stepped care model, where most patients tend to initially receive brief and low intensity interventions before accessing more intensive psychological therapies if required. Recent studies have shown that some patients with more complex clinical presentations tend to drop out and have poor outcomes in low intensity treatments, but they respond better to high intensity treatments. These studies have suggested that referring 'complex cases' directly to high intensity treatments (stratified care) could considerably improve their likelihood of improvement in depression symptoms. The aim of this study is to compare the effectiveness of a stratified care model (where complex cases are matched to high intensity treatments) versus usual stepped-care.

Who can participate?
Therapists and their patients who are eligible for treatment in IAPT

What does the study involve?
Therapists (and patients they assess) are randomly allocated to the StratCare group or the usual care control group. Therapists in the StratCare group are trained to use a computer programme that helps them to identify complex cases and to adequately refer these to high intensity treatments. Control group therapists assess patients and make referrals for treatment in the usual way (based on their clinical judgment and following stepped care principles). Participants' depression and anxiety are measured before and after treatment.

What are the possible benefits and risks of participating?
The StratCare treatment selection method may result in improved depression symptoms for patients classified as having a complex clinical profile. It is not expected that taking part in the study will lead to any disadvantages or risks to therapists or to any patients.

Where is the study run from?
1. Lancashire Care NHS Foundation Trust (UK)
2. Rotherham, Doncaster and South Humber NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2018 to December 2019

Who is funding the study?
MindLife UK

Who is the main contact?
Dr Jaime Delgadillo
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Study website
https://www.stratcare.co.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
152958

Study information

Scientific Title
Pragmatic randomised controlled trial of a stratified care model for depression and anxiety

Acronym
StratCare

Study objectives
Patients in the StratCare group will have significantly greater improvement in depression symptoms after psychological treatment, compared to those in the usual care control group. It is expected that this effect will be found specifically in the subsample of patients classified as complex cases at the time of initial assessment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 18/07/18, ref: 18/WS/0114

Study design
Pragmatic cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
https://www.stratcare.co.uk/information/

Health condition(s) or problem(s) studied
Common mental health problems (depression, anxiety)

Interventions
Psychological therapists who carry out mental health assessments in routine primary care services will be randomly assigned to an experimental group (StratCare) or a usual care control group.

Therapists in the experimental group will have access to a computerized artificial intelligence programme called the StratCare App. The programme prompts therapists to enter (fully anonymized) data for patients who they assess, and uses a machine learning algorithm to recommend a specific type of psychological treatment, based on each patient's characteristics.

Control group therapists will assess patients and make referrals for treatment in the usual way (based on their clinical judgment and following stepped care principles).

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Depression measured using PHQ-9 pre (initial assessment) and post-treatment (final therapy session)

Secondary outcome measures
1. Anxiety measured using GAD-7 pre (initial assessment) and post-treatment (final therapy session)
2. Treatment dropout rates, as recorded in routine clinical records
3. Therapists' adherence to the StratCare treatment recommendations, as measured by statistical reliability indices (hit rates, and treatment-matching precision scores)
4. Cost-effectiveness of the StratCare model by comparison to usual care, determined using a cost-effectiveness acceptability curve (CEAC)

Overall study start date
06/08/2018

Completion date
20/12/2019

Eligibility

Key inclusion criteria
1. Consenting psychological wellbeing practitioners and psychotherapists that carry out routine assessments in an IAPT service (Improving Access to Psychological Therapies programme in England)
2. Therapists who are employed by a participating IAPT service on a permanent contract, or temporary staff who have a contract that is at least as long as the expected timescale for the project (1 year)
3. All consenting patients who are assessed by participating therapists, who are deemed eligible for treatment in IAPT, and who attend at least one post-assessment therapy session

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants

760 cases need to be assessed to identify 226 complex cases (target subsample for primary analysis)

Total final enrolment
951

Key exclusion criteria
1. Therapists whose contract is shorter than the expected timescale for the study (1 year)
2. Therapists currently in training, since they are not yet fully qualified to carry out routine assessments
3. Patients who are assessed as ineligible for treatment in IAPT (eg, those who are signposted to other services), or eligible patients who never attend any therapy sessions after an initial assessment contact

Date of first enrolment
13/08/2018

Date of final enrolment
01/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancashire Care NHS Foundation Trust
Preston
United Kingdom
PR1 8UY

Study participating centre
Rotherham, Doncaster and South Humber NHS Foundation Trust
Doncaster
United Kingdom
DN8 5HU

Sponsor information

Organisation
University of Sheffield

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Sponsor type
University/education

Website
https://www.sheffield.ac.uk/psychology/index

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Industry

Funder Name
MindLife UK

Results and Publications

Publication and dissemination plan
Additional documents, including a full study protocol, statistical analysis plan and copies of relevant assessment measures are available upon request from the Chief Investigator. These documents have been pre-registered and independently reviewed via the UK Integrated Research Approval System (IRAS). A full description of the StratCare algorithm has been published in a scientific journal and is publicly available at: https://doi.org/10.1037/ccp0000231

Results of the trial will be published in scientific journals. Results will also be shared with the participating services at local team meetings and through a research newsletter.

Intention to publish date
20/02/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made 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?
Results article		08/12/2021	09/12/2021	Yes	No
HRA research summary			28/06/2023	No	No
Protocol (other)			18/08/2023	No	No