ISRCTN12459454 https://doi.org/10.1186/ISRCTN12459454

IAPT outcome feedback trial

Submission date	Recruitment status	[X] Prospectively registered
07/01/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Psychological interventions (treatments such as counselling, or talking therapy) can be helpful for people with depression and anxiety problems; however not all patients respond well to therapy and some people deteriorate (get worse). Monitoring patients' response to therapy using short questionnaires can be a useful way to identify people who may not be progressing well or might get worse. An individual patient's response during treatment can be compared to so-called "norms" derived by observing how hundreds of similar patients' symptoms change over time. Using this method, it is possible to identify patients who are 'not on track'. Previous studies have shown that alerting therapists and patients when therapy is 'not on track' can actually help to prevent deterioration and to improve outcomes. This method is called 'outcome feedback'. Although outcome feedback (OF) has been shown to be work well in the USA and other European countries, this technology has not been robustly tested in primary care psychological services in the United Kingdom. Our study aims to assess how this technology performs when used for as part of the NHS run IAPT (Improving Access to Psychological Therapies) programme in England.

Who can participate?
Qualified clinicians providing psychological therapies in IAPT services.

What does the study involve?
Psychological therapists are allocated to either the intervention group or control group, depending on their IAPT service. Those in the control group treat their patients as usual. Those in the intervention group track the progress of all their patients by asking them to fill in questionnaires on how they are feeling. The results from the questionnaires are plotted onto a chart which shows changes from session to session. These results are compared with a chart showing the expected rate of improvement over the course of the treatment. Patients that are "not on track" are then identified so that appropriate action can be taken.

What are the possible benefits and risks of participating?
Patients identified as 'not on track' during therapy may be less likely to deteriorate if they are treated by therapists that use OF. No risks or adverse effects are expected.

Where is the study run from?
Five NHS Trusts in England are taking part.

When is the study starting and how long is it expected to run for?
October 2015 to August 2017.

Who is funding the study?
University of York (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
15/LO/2200

Study information

Scientific Title
Multi-site randomised controlled trial of outcome feedback in IAPT services

Study objectives
Patients with depression / anxiety symptoms who are potentially at risk of poor outcomes (not-on-track) will be less likely to deteriorate if they are treated by therapists that have access to Outcome Feedback (OF) technology, by comparison to usual psychological care (without OF).

Ethics approval required
Old ethics approval format

Ethics approval(s)

London - City & East NHS Research Ethics Committee, 06/01/2016, ref: 15/LO/2200

Study design
Multi-site open-label cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Psychological therapists will be randomly assigned to an outcome feedback (OF) or usual care control group. OF (the experimental intervention) consists of alerting therapists to cases at risk of poor progress in therapy, using real-time outcome tracking and prediction technology.

OF studies track individual patients' progress using brief questionnaires that measure symptom severity, and the results are plotted into a chart that shows changes from session-to-session. The individual patient's symptoms are routinely compared to a chart showing the expected rate of improvement over the course of treatment, which is derived from treatment records for a comparable clinical population. Depending on how close the patient's progress matches the expected recovery chart, cases are flagged up as 'on track' or 'not on track', and feedback about this is provided to clinicians and patients. This feedback system can be integrated within existing electronic clinical information systems used in routine practice to keep case notes and client data. Research in this field demonstrates that using OF methods can help to improve outcomes for patients at risk of poor progress.

Intervention Type
Other

Primary outcome(s)
Changes in patient-reported depression (PHQ-9), anxiety (GAD-7) and functional impairment (WSAS) questionnaires, measured at each therapy session.

Mean changes in these measures at the end of therapy will be estimated for all patients treated by therapists in the intervention(OF) and control groups, therefore patient data is nested within their respective therapists. Comparisons will be made in the mean differences in the above outcomes between groups.

Key secondary outcome(s))
1. De-identified clinical and demographic characteristics for patients treated by the participating therapists (diagnosis, age, gender, ethnicity, socioeconomic deprivation, employment, type and duration of psychological treatments received)
2. A battery of questionnaires completed by participating therapists (includes information on clinical practice, training, experience, supervision, job stress & satisfaction, decision-making and coping styles)

Completion date

01/08/2017

Eligibility

Key inclusion criteria
Qualified clinicians delivering evidence-based psychological therapies in IAPT* services.

* IAPT = Improving Access to Psychological Therapies, a national programme of mental healthcare in England, United Kingdom.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Therapists who are not yet fully qualified (e.g. trainees)
2. Qualified therapists whose work contract is shorter than the active study period (1 year)

Date of first enrolment
22/01/2016

Date of final enrolment
29/02/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Whittington Health NHS Trust
Magdala Ave
London
United Kingdom
N19 5NF

Study participating centre
Barnet, Enfield and Haringey Mental Health Trust
London
United Kingdom
EN1 3SZ

Study participating centre
Pennine Care NHS Foundation Trust
Hyde
United Kingdom
SK14 2BJ

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trial
Cambridge, Huntingdon, Fenland
United Kingdom
CB21 5EE

Study participating centre
Cheshire and Wirral Partnership NHS Foundation Trust
Cheshire
United Kingdom
CW7 2AS

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
University/education

Funder Name

University of York

Alternative Name(s)
The University of York, York, Ebor, Universitas Eboracensis

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018		Yes	No
HRA research summary			26/07/2023	No	No
Other publications	Cost-effectiveness of feedback-informed psychological treatment: Evidence from the IAPT-FIT trial	24/04/2021	26/10/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes