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Investigating the feasibility of inducing a pointless habit using mobile app technology, as a novel interventional component of habit reversal therapy (HRT) for treating obsessive compulsive disorder (OCD)

Submission date
03/02/2020

Recruitment status
No longer recruiting

Registration date
11/08/2021

Overall study status
Completed

Last Edited
10/09/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Obsessive compulsive disorder (OCD) is a common mental health condition where a person has obsessive thoughts and compulsive behaviours. We propose to test the feasibility of utilising Mobile App technology to facilitate a new pointless but non-problematic habit which will then be used alongside exposure and response prevention (ERP) treatment to help enhance the ERP during treatment of OCD patients.

Who can participate?
People aged 18 – 65 years with OCD.

What does the study involve?
Participants will be randomly allocated to one of the two treatment groups, which are Treatment As Usual (TAU) group or Experimental group. If participants are in the TAU group, participants will receive the usual treatment for OCD, which is Exposure and Response Prevention (ERP). But before participants start receiving participants' treatment, participants will be offered an electroencephalography (EEG) test. The EEG will measure participants' brain activity while performing some tasks to assess electrophysiological activity (participants' brain's response to the stimuli). During participants' EEG test participants will complete a simple computerised task that involves judging items and making decisions (participants' choices will be made by pressing buttons). This session will last about 90 minutes and takes place at Rosanne House, Welwyn Garden City.
Once the EEG test is complete, and if participants are allocated to receive the experimental treatment (Habit Reversal Therapy (HRT) combined with Exposure and Response Prevention (ERP), participants will then receive a 40 minutes training from one of the researchers on how to use the Mobile App and on how to practice the "habit sequence task" using a mobile phone Habit Induction App. This app will help participants develop a harmless habit that will then be

used in participants' experimental treatment to help participants extinguish participants' OCD compulsions.
Participants will be asked to practice at home the "habit sequence task" for about 10mins every day for the first six weeks.
Participants allocated to receive Exposure and Response Prevention treatment only, will be invited in visit 3 to attend the outpatient clinic at Rosanne House, Welwyn Garden City to commence weekly treatment programme administered by a therapist.

What are the possible benefits and risks of participating?
To our knowledge, there are no known unacceptable risks associated with Habit Reversal Therapy. However, during exposure to the obsessional situations participants may experience a raised level of distress as participants will not be able to engage in their compulsions but can rely only on the HRT techniques. This effect is common and is often expected to occur during exposure-based behavioural treatment.
EEG devices are not known to be ssaociated with any significant dangers. However, if participants feel any discomfort, they are encouraged to inform the researcher and the necessary actions will be undertaken. The computerised tasks and questionnaires used are not associated with known risks or side effects. If participants do not wish to continue for any reason, they can withdraw from the study at any time.
Participants are unlikely to benefit directly from this study as we are trying to understand how things work. However, it is hoped that this research will contribute to the development of a larger research project that will examine the benefits of Habit Reversal Therapy in OCD.

Where is the study run from?
Hertfordshire Partnership University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2018 to March 2023

Who is funding the study?
1. Wellcome Trust (UK)
2. Hertfordshire Partnership NHS Foundation Trust (HPFT) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
233606

Central Portfolio Management System (CPMS)
39865

Study information

Scientific Title
Investigating the feasibility of inducing a non-maladaptive habit using mobile app technology, as a novel interventional component of habit reversal therapy (HRT) for treating obsessive-compulsive disorder (OCD)

Study objectives
1. The experimental treatment shows evidence of enhancing clinical efficacy, demonstrated as greater clinical improvements in comparison to TAU.
2. The additional improvements associated with the experimental treatment will be sustained for at least 3 months after treatment has terminated.
3. Those with a longer duration of illness, higher levels of baseline habitual activity will respond preferentially to the experimental treatment as compared with TAU.
4. Given that ERP is usually associated with poor adherence and premature discontinuation, those with a history of failing to respond to ERP because of these factors would be expected to show greater clinical improvement on experimental treatment than those allocated to the standard TAU group.
5. The premature discontinuation rate is relatively less than TAU in the experimental treatment group.
6. Co-administration of HRT strategies utilising the induced non-maladaptive habit alongside ERP in OCD, will be accepted and well tolerated by patients with OCD.

7. Relative to the patients randomised to TAU, patients receiving the experimental treatment will show changes in the amplitudes of the electrophysiological brain components following the experimental treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/11/2018, East of England-Cambridgeshire & Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8102; nrescommittee.eastofengland-cambsandherts@nhs.net), ref: 18/EE/0281

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obsessive-compulsive disorder

Interventions
This feasibility study uses treatment manuals or written protocols; the therapists will be trained to provide combination treatment ERP with HRT (experimental treatment) and ERP monotherapy (Treatment As Usual - (TAU)); treatment integrity will be checked e.g. by evaluating an audio recorded session, and an assessor blinded to both treatment conditions will be used to evaluate the pre and post outcome measures.

Study Design

Behaviour
We propose using a quantitative within-group and between-group design where performance will be compared between baseline and endpoint (after 16 hours of face to face treatment) within-subjects as they progress through the treatment-study.

Habit Sequence Task
This task is designed to help the patient develop a new but non-maladaptive habit, by utilising an established mobile application (app) for participants' mobile devices, which will allow them to learn and practice two sequences of finger movements (by tapping their fingers on their phones' screen in an instructed order), composed by chords and single presses. The app is simple and self-instructed, with daily self-paced 10mins training. Participants randomised to the experimental intervention will learn to use the app by face-to-face instruction with the programme designer, followed by homework, until they reach proficiency and automaticity. The training period will usually last for six weeks, at which point the majority of patients are expected to have learnt the habit. However, in those for whom automaticity has not been achieved, a further two weeks training will be offered. The app will record performance data each time they practise in order to test the extent to which they have developed the habit. All such data will be collected online and in real-time. The main output measures will be the

following: time chosen to perform the daily practice (how participants included the task in their daily routine), sequence accuracy and reaction times during training, days till habit acquisition, sequence preferences.

Habit Reversal Therapy (HRT)
An adapted form of habit reversal therapy (Azrin et al 1980) will be utilised as the experimental intervention control/stop engaging in their compulsions during standard ERP sessions, with homework sessions in between appointments. We will monitor the patients' performance of the homework tasks using the real time technology embedded in the mobile app.

Exposure and Response Prevention (ERP)
ERP, a standard behavioural-based intervention for treating OCD, will be delivered alongside HRT in the intervention group and as a monotherapy intervention in the control treatment as usual (TAU) group. In the control TAU group, patients will follow the ERP treatment protocol. They will not use the newly acquired Mob App Habit. They will be encouraged to resist engaging in the compulsion as per standard ERP practice. This will involve face-to-face intervention with the therapist in the clinic with additional planned therapy homework.
In contrast, in the experimental intervention group, the ERP will be modified to include HRT, whereby during the exposure phase, (a symptom provocation exercise), instead of resisting their compulsions whilst waiting for the anxiety to subside independently, the patient will be encouraged to engage in a competing response utilising the newly developed habit as an alternative to performing the OCD compulsion. That is to say the experimental intervention group will be instructed to activate the newly induced habit in place of the compulsion. This will be applied both in the clinic with the therapist and at home as therapy homework. Both the experimental intervention and TAU will be flexibly delivered over 16 hours' with face to face therapist contact, over a period of at least 12 weeks, as per normal clinical practice.

Habit Sequence Extinction
We will assess ongoing habit strength, automaticity and control using the self-report habit index (SRHI) (Verplanken & Orbell 2003). Participants in the experimental intervention group will be assessed on this self-rated scale at regular intervals throughout the study, including for 12 weeks after the termination of treatment, on aspects of habit performance.

Study Procedures

Randomisation Procedure
During visit 2 after the baseline assessment the participant will be randomised in a ratio 1:1 to either the experimental intervention or to the TAU control following the randomisation procedure.

First EEG and Mobile App Habit Induction Training (90 mins)
During visit 2* after the randomisation process the participants randomised to the experimental intervention will undergo the first EEG testing while performing a computerised task and then the Mobile App Habit Induction training. They will be provided with the software designed to run on a mobile phone device (app). For those participants who do not have a mobile phone, one will be provided free of charge for the duration of the study. The Mobile App "habit sequence task" comprises the learning and practising of two sequences of finger movements (by tapping their fingers on their phones' screen in an instructed order), composed by chords and single presses. It is very similar to playing 2 small melodies on a piano. These participants will be asked to practice as instructed on a daily basis for 10 mins for the following six weeks. Participants will do their training at home, comfortably, and without fears of being assessed. During the 6-week-long App practice period, the patient will receive a telephone call once a

week from the Mobile App Trainer to check adherence and manage any problems. Any difficulties experienced by patient in practising the training and the advice given will be recorded.

ERP monotherapy Treatment As Usual (TAU) Group
Visit 3 – ERP Treatment Protocol for OCD (wk1) – (2hrs long)
Participants in the TAU group will meet with the research therapist after one week of being randomised to the TAU group to commence a 2hour long treatment in visit 3, in accordance with the ERP treatment protocol for OCD. The patients will attend therapy on a weekly basis for the duration of the intervention. Subsequent weekly face-to-face therapist assisted session from visit 4 to visit 7 also will each be of 2-hour duration. Thereafter, each therapist-assisted session (visits: 8, 9, 10, 11, 12, and 13) will involve one-hour long face-to-face contact.

Combined ERP/HRT - Experimental Group
Visit 3 and Visit 3* – Habit Review (wk6 and wk8*) – (2hrs long)
Participants randomised to experimental treatment will meet with the research clinician, at Rosanne House, who will review with them the training homework and record with them their lived experience of using the App during the training period including the usefulness of the telephone support, using a semi structured interview. The participant will then be asked to demonstrate the learnt habit for the researcher. An objective rating of the degree of automaticity of
the habit will be made using the SRHI (Verplanken & Orbell, 2003) and also specific analyses of the quantitative data resulted from the Mobile App training during the six weeks performance, such as sequence timings and time frame between moves, as well as from a live demonstration during visit 3. Furthermore, a dual task will be used to assess whether the sequences can be performed without cognitive effort. This comprises of a 1-minute performance of the six weeks practised sequences, simultaneously with a second attention-demanding task. A subjective feedback of the degree of automaticity of the habit will also be elicited.

Visit 4 – Experimental Treatment Intervention (wk7) – (2hrs long)
The patients commence the 2-hour long treatment during visit V4 of week 7, at Rosanne House, provided the patient demonstrated automaticity in the new learnt habit. Subsequent weekly face-to-face therapist assisted sessions from visit V5 of week 8 up to visit V8 of week 11, will also be 2-hour long each. Thereafter, each therapist-assisted session, from visit V9 of week 12 to V14 of week 17, will also involve one-hour face-to-face contact.
However for those patients who fail to achieve automaticity, in the new learnt habit after the first six weeks Mobile App training, a further two weeks training will be provided. At the end of the two weeks, the patient will attend Rosanne House in visit labelled V3* (week 8*) to further assess attainment of automaticity in the new habit. The patient will then commence treatment at Rosanne House, in visit V4, (which taking place in week 9), irrespective of the degree of automaticity. Furthermore, the timing of the subsequent visits (and duration of the study) will also be extended by 2 weeks. Therefore a patient commencing treatment in V4 of week 9 is expected to complete the study program in visit 14 of week 19.
In view of the fact that seven or nine weeks will have elapsed since the baseline, and in order to ascertain the effect of habit training on core OCD symptomatology the following ratings will be repeated to provide a pre-treatment baseline: YBOCS (primary outcome), State/Trait Anxiety Questionnaire, MADRS, Sheehan disability scale, and the SRHI. After the participant has completed the measures, the participant is then seen by the therapist to commence treatment using a modified ERP/HRT protocol.
The patients will attend therapy on a weekly basis for the duration of the intervention. Each of

the first six therapist assisted sessions (visit 4, 5, 6, 7 and, 8) will involve 2-hrs face-to-face contact. Each of the remainder of the therapist assisted sessions (visit 9, 10, 11, 12, 13, and 14) will involve one-hour face-to-face contact.

Visit 5(wk8) – Visit 14(wk17)
Therapist and patient evaluate previous homework and treatment adherence by reviewing their scores on the Likert scales in addition; the App will record real time usage as supplementary measure of adherence for the participants receiving the experimental intervention. If the patient has successfully completed their homework and the urge to perform the compulsion has reduced to the extent the patient no longer considers it to be a distressing compulsion, and the patient can disregard the compulsion with ease, then the therapist and the patient collaboratively choose another situation higher-up the hierarchy. If the urge to perform the extinguished compulsion re-emerges at any time they are encouraged to resist the urge and in the case of the experimental intervention group, the patient will be asked to apply the learnt habit until the urge subsides. In cases when the urge has failed to abate and continues to remain a problem, the patient will continue to practice the previous week's homework until the next visit. The patients' progress up the exposure hierarchy is therefore dependent on their progress with their previously assigned homework and will be evaluated as a treatment outcome.

Visit 8 (wk11) – Mid-point Data Collection
Mid-point clinical data will be collected using YBOCS, MADRS, Sheehan, and STAI in Visit 8 before the patient commences the treatment for that visit.

Visit 14 (wk17) – Post-treatment Data Collection Intervention, EEG & Study Ends – (4hrs long)
In advance of seeing the therapist for the final review of their homework, the patient will meet with the trained researcher to evaluate both clinical and cognitive data. The researcher will collect the data using the following instruments:
a) The Yale Brown Obsessive Compulsive checklist and scale (YBOCS) (Goodman et al., 1989).
b) MADRS (Montgomery & Asberg, 1979)
c) Sheehan Disability Scale (Sheehan, 1983)
d) State/Trait Anxiety Questionnaire (Spielberger et al., 1983)
e) The Intradimensional / Extradimensional Shift task (IED) (CANTAB) (Robbins et al., 1994)
f) Self-report habit Index (SRHI) (Verplanken & Orbell 2003 (for experimental treatment group only)
g) Intolerance of Uncertainty Scale (IUS) (Carleton, Norton, & Asmundson, 2007)
h) Second EEG testing

The therapist will review the patient for one last time and the patient will be discharged from the study to the service they originally came from with a recommendation as to whether further treatment for OCD is required.

End of Study Definition
The Research Ethics Committee (REC) will be informed that the study has been completed when the last participant in the study has completed his/her last interview of week 16.

Intervention Type
Behavioural

Primary outcome(s)

1. Presence of OCD measured using the Yale Brown Obsessive Compulsive Symptom (YBOCS) Checklist at baseline screening and again at end of study at 12 weeks.
2. OCD symptoms measured using Yale Brown Obsessive Compulsive Scale (YBOCS) at baseline (Week0), midpoint (week6) and at study end (end of the 12 sessions treatment programme)

Key secondary outcome(s)
1. The MINI International Neuropsychiatric Interview (M.I.N.I.) questionnaire at baseline used both for inclusion purposes to confirm the diagnosis for OCD and for exclusion purposes to screen for Major Depressive Disorder (MDD), Alcohol and Substance Misuse and Psychotic Disorders.
2. National Adult Reading Test (NART) to measure verbal intelligence. It is simply a measure of scholarity at baseline
3. Edinburgh Handedness Inventory (EHI) to measure a person's right or left hand dominance in everyday activities at baseline
4. MADRS for measuring the severity of depressive symptoms at baseline, at 6 weeks and at 12 weeks
5. Sheehan Disability Scale (SDS) to evaluate the impact of the patient’s symptoms/illness on three areas of functioning: work, social and family at 6 weeks and at 12 weeks.
6. State/Trait Anxiety Questionnaire (STAI) to report the anxiety feelings currently experienced by the participant at the present moment at baseline, at 6 weeks and at 12 weeks
7. Self Report Habit Index (SRHI) for measuring habit strength and automaticity at baseline, 6 weeks and at 12 weeks.
8. Intolerance of Uncertainty Scale measures the unpleasantness of uncertainty at 6 weeks and at 12 weeks
9. The Intradimensional / Extradimensional Shift task (IED) (CANTAB) measuring the participant’s ability to withhold/sustain their attention to certain rules displayed on a computer screen at baseline, at 6 weeks and at 12 weeks
10. Electroencephalography (EEG) analyses to record electrical activity in the brain at baseline, 6 weeks and at 12 weeks

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Obsessive-Compulsive Disorder as a diagnosis confirmed using the MINI International neuropsychiatric inventory
2. Minimum OCD symptom severity score of 17 based on the Yale Brown Obsessive Compulsive Scale (YBOCS)
3. Medication for OCD will be allowed (SSRI, clomipramine, adjunctive antipsychotic) as long as the formulation and dose remains unchanged for 16 weeks before the study and for the total duration of the study
4. Have a use of a smartphone but patients without easy access to it will be provided with a mobile device that runs the app
5. Aged 18 to 65 years old
6. Adequate use of English to understand the study documentation and participate in the rating assessments
7. Capable of giving consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Severe Major Depressive Disorder with a score of at least 35 as measured by the Montgomery-Asberg Depression rating Scale (MADRS)
2. Severe suicidal ideation with a score of 4 or greater on the MADRS
3. Past or present psychotic episodes
4. Meets DSM-V criteria for substance abuse or dependence
5. Severe physical impairments affecting eyesight or motor performance, as this may affect performance on behavioural tasks
6. Any changes in dosage or formulation of medication known to be efficacious in OCD in the previous 16 weeks

Date of first enrolment
01/02/2019

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

England

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Hertfordshire Partnership University NHS Foundation Trust
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Sponsor information

Organisation
Hertfordshire Partnership University NHS Foundation Trust

ROR
https://ror.org/0128dmh12

Funder(s)

Funder type
Government

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Hertfordshire Partnership NHS Foundation Trust

Results and Publications

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?
Abstract results	ACNP 62nd Annual Meeting: Poster Abstract P413.	01/12/2023	10/09/2025	No	No
HRA research summary			28/06/2023	No	No