

Habit as a therapeutic component in psychological treatment for obsessive-compulsive disorder: A randomised controlled feasibility study¹☆

Ana Maria Frota Lisboa Pereira de Souza^{a,b,c,2,*}, Davis Mpavaenda^{a,d,2}, Paula Banca^{b,e,f}, David Wellsted^a, Janine Hopkins^d, Aleya A. Marzuki^{b,g,h}, Monika Lee^d, Evmorfia Karafylli^d, Olga Bardsley^d, Sabina Mazoruk^d, Stefanie Skalecki^d, Shanti Boodhun^d, Hannah Mendoza-Wolfson^d, Claire Crispin^d, Rebecca Aloneftis^d, Deela Monji-Patel^d, Eduardo Cinosi^d, Luca Pellegrini^{a,d,i,j}, Arun Enara^{d,k}, Seema Panjwani^d, Maham Riaz^d, Stacey Oliver-Singleton^d, Trevor W. Robbins^b, Naomi A. Fineberg^{a,d,l}

^a School of Life and Medical Sciences, University of Hertfordshire, Hatfield AL10 9AB, UK

^b Behavioural and Clinical Neuroscience Institute, Department of Psychology, University of Cambridge, Cambridge CB2 3EB, UK

^c ORCHARD-Advancing Global OCD Research, Cambridge CB1 2BL, UK

^d Hertfordshire Partnership University NHS Foundation Trust, Welwyn Garden City AL8 6HG, UK

^e Department of Neuroscience, Faculty of Medicine and Nursing, University of the Basque Country, UPV/EHU, Vitoria-Gasteiz, Spain

^f IKERBASQUE, Basque Foundation for Science, Bilbao, Spain

^g Department of Psychiatry and Psychotherapy, Medical School and University Hospital, Eberhard Karls University of Tübingen, Tübingen, Germany

^h German Center for Mental Health (DZPG), Tübingen, Germany

ⁱ Department of Medicine, Surgery and Health Sciences, University of Trieste, 34149, Italy

^j Azienda Sanitaria Universitaria Giuliano-Isontina – ASUGI, UCO Clinica Psichiatrica, Trieste 34138, Italy

^k North London NHS Foundation Trust, London NW1 0PE, UK

^l University of Cambridge School of Clinical Medicine, Cambridge CB2 0SP, UK

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ABSTRACT

Introduction: Cognitive-behavioural therapy (CBT) with exposure and response prevention (ERP) represents a first-line intervention for obsessive-compulsive disorder (OCD), but many patients either do not tolerate or respond to it. Habit-reversal therapy (HRT) is used to treat a variety of disorders characterised by repetitive behaviours. HRT involves learning a non-pathological motor habit to help extinguish repetitive behaviour. Augmenting ERP with components of HRT represents a novel candidate treatment approach for OCD.

Aims: A randomised controlled trial (RCT) investigating the feasibility, acceptability, tolerability, and effectiveness of CBT + ERP augmented with a non-pathological habit in patients with OCD.

Methods: Forty-five treatment-seeking individuals with OCD were randomly allocated to 12 weeks CBT + ERP augmented with a smartphone-induced habit, comprising a learnt finger sequence, applied during exposure ($N = 22$) or 12 weeks CBT + ERP ($N = 23$) as the control. Participants randomised to the experimental arm underwent 6–8 weeks habit-training first. Participants were assessed using blinded-raters for OCD severity (Yale-Brown Obsessive-Compulsive Scale; Y-BOCS) (primary outcome), depression (Montgomery-Åsberg Depression Rating Scale; MADRS), anxiety (State-Trait Anxiety Inventory-State; STAI-S), intolerance of uncertainty (Intolerance of Uncertainty Scale; IUS), and functional disability (Sheehan Disability Scale; SDS). We applied a conservative, intent-to-treat (ITT) analysis using the last observation carried forward (LOCF).

Results: Twenty-eight (62%) participants (CBT + ERP + Habit = 11; CBT + ERP = 17) completed the trial. There was a significant reduction in Y-BOCS during habit-training ($p < .05$), prior to initiation of any psychological treatment. There were no significant between-arm differences on the Y-BOCS or any other clinical rating, nor in

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* Corresponding author at: School of Life and Medical Sciences, University of Hertfordshire, Hatfield AL10 9AB, UK.

E-mail address: af23aab@herts.ac.uk (A.M.F.L. Pereira de Souza).

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² Joint first authorship.

premature discontinuation rates at the endpoint. However, a larger number of participants dropped out during the habit training phase (7/22). Reported adverse events (measured during the treatment phase) were significantly fewer in the experimental arm ($p < .001$). Equivalent within-group improvement was seen in both arms on the Y-BOCS and IUS (all $p < .05$). Only those within the control arm experienced improvement in the MADRS ($p < .01$) and SDS ($p < .05$). Anxiety did not change in either arm.

Conclusion: This small feasibility study limited by methodological confounds suggests habit-augmented CBT could be efficacious and well-tolerated in OCD. The improvements resulting from habit-training alone were unexpected and suggest novel treatment-approaches activating motor systems for OCD merit further investigation.

How use doth breed a habit in a man!

The Two Gentleman of Verona, Act V, Scene 4

William Shakespeare

1. Introduction

Obsessive-compulsive disorder (OCD) is a condition marked by the inflexible performance of stereotyped compulsions, which may reflect, at least in part, an overreliance on habitual behaviour [1–5]. Abundant evidence implicates a role for urges and inhibitory control deficits in OCD [6–9]. The fast and involuntary character of habits, which require limited thought to be performed, renders them relatively impervious to cognitive and inhibitory control [10–15]. Thus, habitual mechanisms may represent a core element of the psychopathology of compulsions and a new treatment target for OCD [16].

International treatment guidelines have established a combination of cognitive-behavioural therapy (CBT) and exposure and response prevention (ERP) as first-line psychotherapeutic strategies for OCD [17,18]. ERP is practised through the creation of a hierarchy of situations that trigger obsessive-compulsive symptoms. During ERP, the patient is exposed to these situations gradually, and will practise not performing the compulsion, until the highest level on the hierarchy is achieved. A number of theories have been proposed to explain the efficacy of ERP in OCD [19]. One assumes that ERP works by first activating a ‘fear structure’ [20] and then breaking the fear-based associations by habituation. Another model assumes ERP works by strengthening the learning of new and safe associations that oppose the harm-related fears. New information that shows the situation is safe is created to compete with previously learnt associations, thereby allowing the individual to replace the learnt association with threat with a safer one [21]. In either case, ERP seems to work through a process of preventing a previously reinforced and automatic behaviour from taking place, in a manner akin to breaking a ‘stimulus-response’ (S-R) habit [22,23].

Evidence from clinical studies suggests that CBT with ERP is only effective in approximately 50% of clinical cases [20,24–26]. Some individuals drop out of ERP due to beliefs that the exposures are ‘too difficult’ to perform [27], or that the anxiety provoked by ERP is ‘too intense’ to bear [28,29]. In the recent meta-analyses by Reid et al. (2021) [26], it was found that other forms of psychological therapy showed similar levels of effectiveness to ERP, suggesting that the psychological therapy profile for OCD could be broadened. Additionally, it is estimated that around 20% of individuals with OCD will not respond to any of the available treatments [30]. It is imperative, therefore, to identify novel interventions with better effectiveness, to improve the quality of life of individuals with this highly debilitating disorder [31,32].

Amongst new strategies proposed to address this issue, habit-reversal therapy (HRT) has recently been gaining attention and interest [7,16]. Established already as a treatment option for tic disorders, trichotillomania, and ‘habit disorders’, i.e., conditions marked by repetitive behaviours that serve no adaptive function [33–38] and considering the established relationship between OCD and tic disorders, including the substantial evidence linking the two, both diagnostically and in terms of

shared treatment approaches [39], a logical next step would be to test HRT in OCD itself [7,16,30,40–42]. Indeed, two studies have examined the benefits of HRT in OCD through case studies, finding promising results [40,42]. Toffolo and Saxena (2019) [42], for instance, tested the technique in four participants, who showed between 30 and 50% improvement in OCD severity. Moreover, the participants rated the treatment as acceptable and effective, corroborating the results from the single case study by Dillenburger (2006) [40]. Nevertheless, the absence of a randomised clinical trial hinders the ability to properly evaluate the feasibility and effectiveness of this technique.

HRT comprises several components including: (i) awareness training; (ii) competing-response practice; (iii) habit-control motivation; and (iv) generalisation training [16,33,40]. Whilst aspects of components i, iii, and iv are already incorporated into standard CBT + ERP protocols, with anxiety tolerance and response *prevention* being emphasised [43], competing-response practice differs, with suppression being used as the competing-response in ERP, and engagement in a learnt habit being the competing response in HRT. This contrast between preventing a response from taking place and engaging in a different motor response taps into the motor aspects of the condition whilst maintaining the S-R disruption [44]. Whilst both of these forms of competing response overlap functionally, in terms of depending on inhibitory brain mechanisms [45], the former relies on pure suppression (i.e. no response taking place), while the latter includes engagement in different motor actions, thereby activating different brain areas and cognitive structures [46–51] (see Fig. 3 in the supplementary material). Suppression abilities, which fall in the remit of the robustly evidenced inhibitory control deficits in OCD [52], are known for engaging prefrontal brain areas. Conversely, the selection and performance of actions activates motor areas, which are also engaged in the generation of urges [8]. Allowing patients the possibility of performing an alternative motor action instead of the compulsion may consist of an outlet for the motor build-up (urge) to perform the compulsion, which could be beneficial.

1.1. Aims

We designed this randomised controlled feasibility study as a first step to evaluate the acceptability, tolerability, and efficacy of augmenting CBT with ERP with the competing-response practice component of HRT, i.e., by introducing a competing habit during exposure exercises to aid extinction of the compulsions.

We hypothesised that:

- Co-administration of HRT strategies utilising the induced competing habit (a sequence of finger movements) alongside ERP in OCD will be accepted and well tolerated by patients with OCD.
- Introducing a learnt non-pathological habit to ERP (CBT + ERP + Habit) would produce better clinical outcomes including improved efficacy and tolerability compared with a control treatment comprising treatment as usual with CBT with ERP (CBT + ERP).

We applied a mechanistic analysis including cognitive and electroencephalographic (EEG) assessments to investigate the mechanisms of effect of habit augmented CBT in OCD. These outcomes will be reported

separately. This paper focuses exclusively on the clinical outcomes linked to the new intervention.

2. Methods

2.1. Research ethics approval

The study was approved on July 2018 by the East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (18/EE/0281) and registered by the Health Research Authority (HRA) (IRAS: 233606). It was pre-registered as a clinical trial in the ISRCTN registry (Trial ID: ISRCTN69935306). Recruitment and data collection were conducted from March 2019 to November 2022. Of note, the study partly took place during the COVID-19 pandemic.

2.2. Consent

All participants signed an informed consent form prior to screening, and then again prior to starting study procedures.

2.3. Participants

2.3.1. Recruitment

Participants were treatment-seeking patients referred by their local (Hertfordshire) secondary healthcare mental health teams (Community Mental Health Services (CMHS)) or primary healthcare Improving Access to Psychological Therapies (IAPT) services. They were identified and invited to take part in the feasibility trial by their treating clinicians.

2.3.2. Screening

An experienced clinician specialised in the assessment and treatment of OCD (DM) screened individuals to ensure eligibility for the study through a detailed demographic questionnaire. We applied broad eligibility criteria to strengthen the generalisability of our sample. Inclusion criteria were: (i) being aged 18 to 65 years old; (ii) having OCD as a DSM-IV diagnosis confirmed by a clinician (DM) using the MINI version 5.0.0 [53]; (iii) having a minimum OCD symptom severity score of 17 based on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) [54]; (iv) maintaining a dose of medication unchanged for 16 weeks prior to the start of the study and for the total duration of the trial; (v) having adequate use of the English language to understand the study documentation and participate in the rating assessments; and (vi) being capable of consenting to the study.

Participants were excluded if: (i) they endorsed criteria for severe major depressive disorder with a score of at least 35 as measured by the Montgomery-Åsberg Depression Rating Scale (MADRS) [55]; (ii) they presented severe suicidal ideation, as measured by a score of 4 or greater on the relevant question on the MADRS (item 10); (iii) there was presence of past or present psychotic episodes; (iv) they met DSM-IV criteria for current substance abuse or dependence; and (v) there was presence of severe physical impairments affecting eyesight or motor performance that might interfere with performance of the habit.

2.4. Materials and procedures

2.4.1. Staff roles and training

Therapists in the study were recruited from the Hertfordshire Partnership Foundation Trust (HPFT) primary and secondary mental healthcare teams, consisting of nurses, psychologists, and occupational therapy support workers. A requirement for therapists was experience in treating mental health conditions using psychological techniques and an active case load of participants, regardless of professional background. They underwent dedicated training on the study protocol and the psychological techniques by the principal investigator prior to the start of the study, and those completing training were offered continuing professional development (CPD) certificates. Nine out of the 11 trained

therapists went on to actively participate in the trial. Trial therapists were required to attend weekly supervision, which ran from 15 February 2019 to 31 March 2023 led by the principal investigator and focused on maintaining adherence to the treatment protocols, preventing therapy from drifting to non-OCD issues, managing and reporting risk factors, monitoring adverse events (AEs) or side effects, and addressing challenges faced by therapists. Once a therapist committed to treating a patient, the number of hours specified in the protocol was followed, and no changes in therapists occurred during the trial.

2.4.2. Outcome assessment

Observer-rated clinical outcomes (apart from AEs) were collected by blinded-raters, comprising doctors specialising in Psychiatry, who undertook in-person training on the relevant measures with an experienced psychiatrist (NF). Raters were only included once they had demonstrated adequate performance on rating a standard videotaped case. A single dedicated researcher (AMFLPS) delivered the remaining non-clinical aspects of the study, including cognitive and EEG assessments (to be reported separately).

2.4.3. Adverse events (AEs) monitoring

A particular emphasis was given to AE reporting, both during each therapy and homework session. A broad definition for AEs was used, to include symptoms of anxiety, distress, and other mental phenomena as well as physical events. AEs were routinely enquired about by the therapists at each therapy session and recorded in the trial clinical record. AEs were not routinely monitored during the habit training phase, nevertheless, spontaneous reports were recorded.

2.5. Design

An illustration depicting the stages of the study can be found in Fig. 1 of the supplementary materials. Following screening, eligible consenting participants were invited to the first face-to-face session with the research team.

2.5.1. Baseline assessment

Baseline assessment was conducted by a trained clinician, blinded to treatment allocation. Assessment included observer-rated evaluation of OCD severity using the Y-BOCS together with its obsession and compulsion subscales [54] and depressive symptoms with the MADRS [55]. We additionally used self-report measures of functional disability (Sheehan Disability Scale – SDS) [56], state anxiety (State-Trait Anxiety Inventory – STAI-S) [57], and intolerance of uncertainty (Intolerance of Uncertainty Scale – IUS-12) [58].

2.5.2. Randomisation

Randomisation into groups occurred after the baseline assessment and was achieved using a computer-generated sequence to ensure assignment to each arm took place according to required probabilities (1:1). Allocation was administered by an independent researcher administrator who was not involved in the assessment of participants.

2.5.3. Mobile application for inducing a non-pathological habit and app-training

Participants randomised to the CBT + ERP + Habit arm received training from an unblinded researcher to reach automaticity on a sequence of finger movements using a mobile application developed by Banca and colleagues [59]. Participants were instructed to learn two novel sequences of finger tapping movements, similar to playing keys on a piano, and to practise each sequence twice a day for at least 6 weeks. A sequence consisted of six random finger tapping movements, which could use one, two, or three simultaneous fingers of the participant's dominant hand (index, middle, or ring). A complete practice consisted of 20 correct sequences, and both sequences were required to be practised twice daily (Fig. 1). A calendar on the initial screen of the app guided

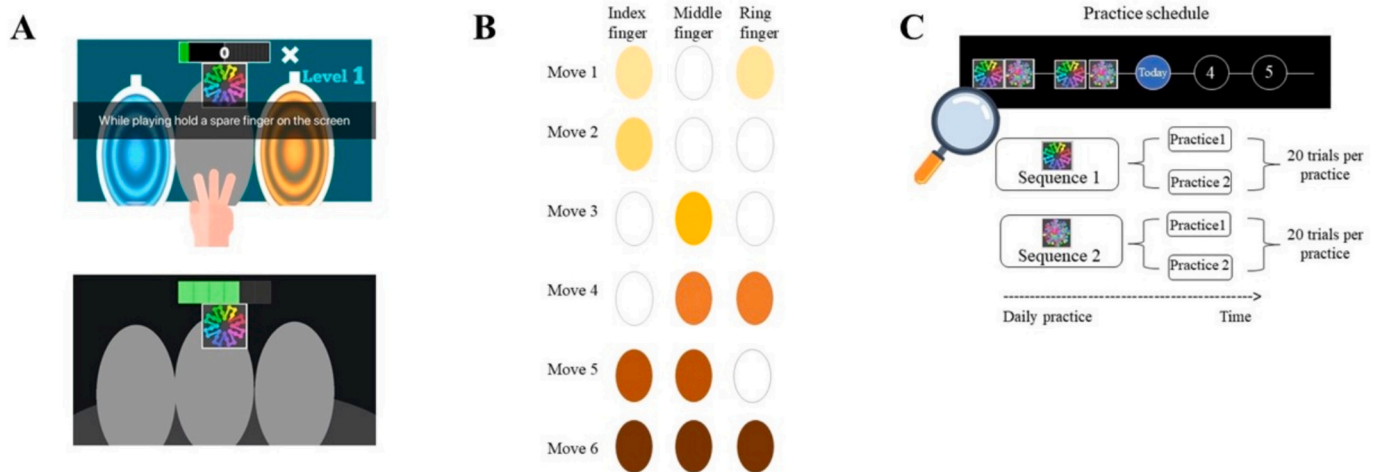


Fig. 1. Schematic representation of the app, the finger sequence, and the daily practice schedule.

Panel A. Top: layout of the app with coloured circles initially guiding participant. Bottom: App not presenting any clues to guide the sequence performance at later stages of the training, as it detects patients' full knowledge of the sequence. Panel B. Example of a sequence. Panel C. Daily practice schedule. Adapted from Banca et al., 2020.

participants on their training, and any missed days would have to be compensated for to progress with training. Habit learning was continually monitored online by the researcher through a server, and the researcher would contact participants if the recommended training was not being achieved.

Automaticity was assessed at the end of the six-week training period in a face-to-face session with the principal investigator, who would evaluate participants' proficiency when performing the movements and ask about their experience with the app. Specifically, participants were asked if they had to think about the sequences when playing or if they could be performed habitually. Participants who had not achieved automaticity were asked to practise the sequences for an additional two weeks, when automaticity was tested once more.

2.5.4. Second assessment

Participants in both arms were invited for a second assessment, which took place at the end of week 6 for those randomised to CBT + ERP, corresponding to completion of six sessions of CBT + ERP (for details, see below), and at week 7 or 9, i.e. within one week of completing habit training (as the automaticity assessment took place at week 6 or 8) for those randomised to the habit-augmented arm (see above). This second assessment represented a new baseline assessment (pre-therapy baseline) for those in the habit-augmented arm as it took place just prior to starting the therapy phase.

At this assessment, participants completed the Y-BOCS and the MADRS with the blinded rater and the same self-rated scales as applied at baseline. Participants in the CBT + ERP group went on to complete the final six weeks of therapy, whereas those in the habit group started a full 12-week course of CBT + ERP + Habit (for details, see below).

2.5.5. Endpoint assessment

At the final endpoint of the study (week 12 for those in the CBT + ERP arm, week 19 or 21 for those in the CBT + ERP + Habit arm), individuals in both arms were re-assessed using the same measures used at baseline. In addition, those participants completing the CBT + ERP + Habit arm were administered a self-report questionnaire comprising four items, each rated on a Likert scale ranging from strongly disagree to strongly agree. The items enquired how tolerable, acceptable, and impactful augmenting CBT + ERP with a non-pathological habit was, and to what extent they followed the required training.

2.6. Interventions

2.6.1. CBT ± ERP Arm

The therapists followed a protocol specifically designed for the study based on recognised OCD treatment manuals [60,61]. Treatment consisted of 12 weekly CBT + ERP sessions, divided into three stages, namely: (i) psychoeducation; (ii) cognitive and behavioural interventions; and (iii) exposure and response prevention. The first 2 weeks were dedicated to understanding obsessions and compulsions and explaining to participants how to identify those, their triggers, and the emotions associated with them. Homework followed each session. Participants were also taught about the CBT and ERP models and asked to develop their exposure hierarchy list. The remaining sessions focused on classic CBT + ERP techniques, such as reappraisal of thoughts and anxiety habituation [61]. The total duration of treatment was 17 h (the first five sessions had a duration of 2 h each, whilst the remaining seven were one hour long).

2.6.2. CBT ± ERP ± Habit Arm

Following completion of habit-training, those allocated to the experimental arm underwent weekly sessions of CBT + ERP augmented with the learnt finger-sequence habit over a period of 12 weeks. The treatment followed the same protocol as the CBT + ERP arm, with the difference that participants were encouraged to practise the newly learnt habit during exposure and response prevention training. Following the original protocol developed by Azrin and Nunn (1973) [33], participants were taught how to identify the emergence of urges to perform the compulsions and in which situations they performed them more often. It was also explained that they were testing the prediction that it would be beneficial to use the new, competing habit to attenuate the compulsive behaviour. Hence, they were instructed by their trial therapists to practise the contingent use of the new habit (i.e. as the 'competitor' for the compulsions) during exposure exercises. This took place at week 3 of the treatment phase. According to our protocol, the therapist demonstrated to the patient how to correctly carry out the habit-augmented exposure exercise. This involved the participant placing themselves in the chosen exposure situation to trigger or induce or heighten the urge to engage in the compulsion. During the exposure, the therapist modelled the performance of the learnt competing habit to compete with the compulsion. The therapist then asked the patient to deliberately provoke the compulsion by placing himself or herself in the chosen situation and practice the competing habit in front of the therapist to confirm that they

had understood how to carry out the ERP/Habit exposure correctly. Further, the therapist explained to the patient that they should repeat the new habit continuously during the full one-hour duration of the exposure therapy homework exercises or until the urge to engage in the compulsion was attenuated, whichever was achieved first. Outside of therapy homework, they were also encouraged to apply the habit whenever they felt a compulsive urge, this time for a minimum of 3 min or until the urge attenuated. In addition, if the patient had accompanying people for social support, they were asked to remind the patient to use the competing new habit response as instructed during this session. This practice was monitored by the trial therapists during treatment sessions. The total duration of treatment was 17 h (the first five sessions had a duration of 2 h each, whilst the remaining seven were one hour long).

2.6.3. Analysis

An intent-to-treat analysis (ITT) using the Last Observation Carried Forward (LOCF) method was applied to the clinical scores as the primary analysis approach, to account for missing data due to dropouts. All analyses in this paper followed the ITT approach.

2.6.3.1. Habit training phase. The initial baseline scores of the CBT + ERP + Habit arm were used to evaluate the effects of habit-training. Eleven participants achieved automaticity after six weeks training whilst another four required a total of eight weeks. Seven participants did not complete the training phase because they did not complete the second clinical assessment. However, as they had been randomised, we included them in our intent-to-treat analyses. For those who dropped out before or during the training stage, the last observation carried forward (LOCF) method was used to interpolate the missing data. To account for the habit training effect, paired-sample *t*-tests comparing pre and post training measures were conducted.

2.6.3.2. Therapy phase. Independent and paired-sample *t*-tests were used to account for within and between arm differences in therapy outcomes. We included all those randomised to either arm in the analysis, using the last observation carried (LOCF) forward for those who discontinued prematurely. This included those in the CBT + ERP + Habit arm who dropped out of habit training, whose original baseline scores were carried forward, through to the study endpoint. Importantly, the study design resulted in different timepoints for the two groups. For the CBT + ERP + Habit arm, the second assessment, which took place after 6–8 weeks habit training had been completed, provided the new baseline score (pre-therapy baseline) from which to evaluate the effect of the 12 weeks of therapy. In the case of the control treatment, the initial baseline and endpoint scores were used to evaluate the effect of treatment, with the second assessment providing an additional mid-therapy score.

Non-parametric tests were conducted when conditions for parametric tests were violated. An alpha of 0.05 was chosen as a significant threshold. Statistical analyses were conducted on JASP software (JASP Team (2023). JASP (Version 0.17.1) [Computer software]).

3. Results

3.1. Participant flow through the study (Fig. 2)

One hundred and eight (108) participants were assessed for eligibility. Of those, 26 did not match inclusion criteria for the study and 37 withdrew their interest. Forty-five participants ($N = 31$ female - 68.9%) completed the first baseline assessment and were randomised. Out of the 22 participants randomised to CBT + ERP + Habit, 11 (50%) completed the trial. Most discontinuations in this arm occurred during habit training (7 premature dropouts, of whom 3 completed training but did not attend the post-training assessment point). Out of the 23 participants

randomised to CBT + ERP, 18 (78%) reached the mid-therapy rating assessment and 17 (74%) the final assessment. In total there were 6 (26%) dropouts in this arm. The reasons given for discontinuation are depicted in Fig. 2. Although numerically more participants discontinued the habit-augmented arm, analysis showed no significant difference in discontinuation rates across the treatment arms ($\chi^2 = 2.73$, $p = .098$). However, sample sizes were small and so type 2 error cannot be excluded.

3.2. Sample characterisation at baseline

There were no significant demographic differences and baseline clinical scores were similar across both treatment arms (Table 1). The participants in both arms were, on average, moderately symptomatic in terms of OCD (Y-BOCS means 26.91 (SD = 4.2) versus 26.87 (SD = 5.2)), and mildly depressed (MADRS means 15.8 (SD = 9.4) versus 18.1 (SD = 9.7)). Compatible with the clinical status of the study sample, the majority of participants were receiving medication, with only eleven being unmedicated (24.4%). There was no difference in levels of medication between the two treatment arms. Most participants were receiving a serotonin reuptake inhibitor (SRI) as monotherapy, in accordance with OCD medication guidelines [18]. Augmentation agents included quetiapine ($N = 4$), olanzapine ($N = 2$), pregabalin ($N = 2$), mirtazapine ($N = 2$), and amitriptyline ($N = 1$). Two participants in the CBT + ERP arm had motor related comorbidities, with one having a diagnosis of Ehlers-Danlos syndrome and the other being diagnosed with Parkinson's Disease, for which he was medicated with carbidopa and levodopa.

3.3. Phase 1; Habit training

3.3.1. Acceptability, tolerability, and adherence

Seven participants dropped out prematurely during the training phase, four in the earliest stages of training. The reasons for discontinuation are depicted in Fig. 2 and were mixed. Of note, one participant was unable to manage habit training owing to physical problems with their hand. Two others did not start training for reasons related to clinical issues affecting study participation (severity of illness and suicide risk) and one never started practising, which could possibly reflect unwillingness to engage in habit training. The remaining three completed the required training practices, but did not attend the post training (second) assessment for diverse reasons, which resulted in their exclusion.

Adherence to habit training was measured objectively through daily online monitoring of practice by the researcher. On average, the 18 participants who completed the habit training engaged in 76% of the required training days. Participants estimated their adherence to training as between 50 and 100% of what was stipulated, which corroborates the objective adherence monitoring. Fig. 2 in the supplementary materials depicts the training adherence results.

3.3.2. Clinical outcomes of habit training – ITT analysis

Changes in clinical outcomes during the habit-training phase are depicted in Table 2 and Fig. 3. Note, there was no behavioural control for habit training. Non-parametric paired-sample *t*-tests (Wilcoxon signed-rank test; W) utilising the LOCF method and comparing pre- to post-training scores of all clinical measures indicated a significant reduction of the total Y-BOCS score (mean difference = 2.9, SE = 1.04, $p = .013$) and of the obsession (mean difference = 1.454, SE = 0.54, $p = .008$) and compulsion (mean difference = 1.455, SE = 0.55, $p = .02$) subscales. No significant improvements on scores of depression, functional disability, anxiety, or intolerance of uncertainty were found.

3.4. Phase 2; Therapy

3.4.1. Acceptability, tolerability, and adherence

Of the 15 participants starting CBT + ERP + Habit therapy phase,

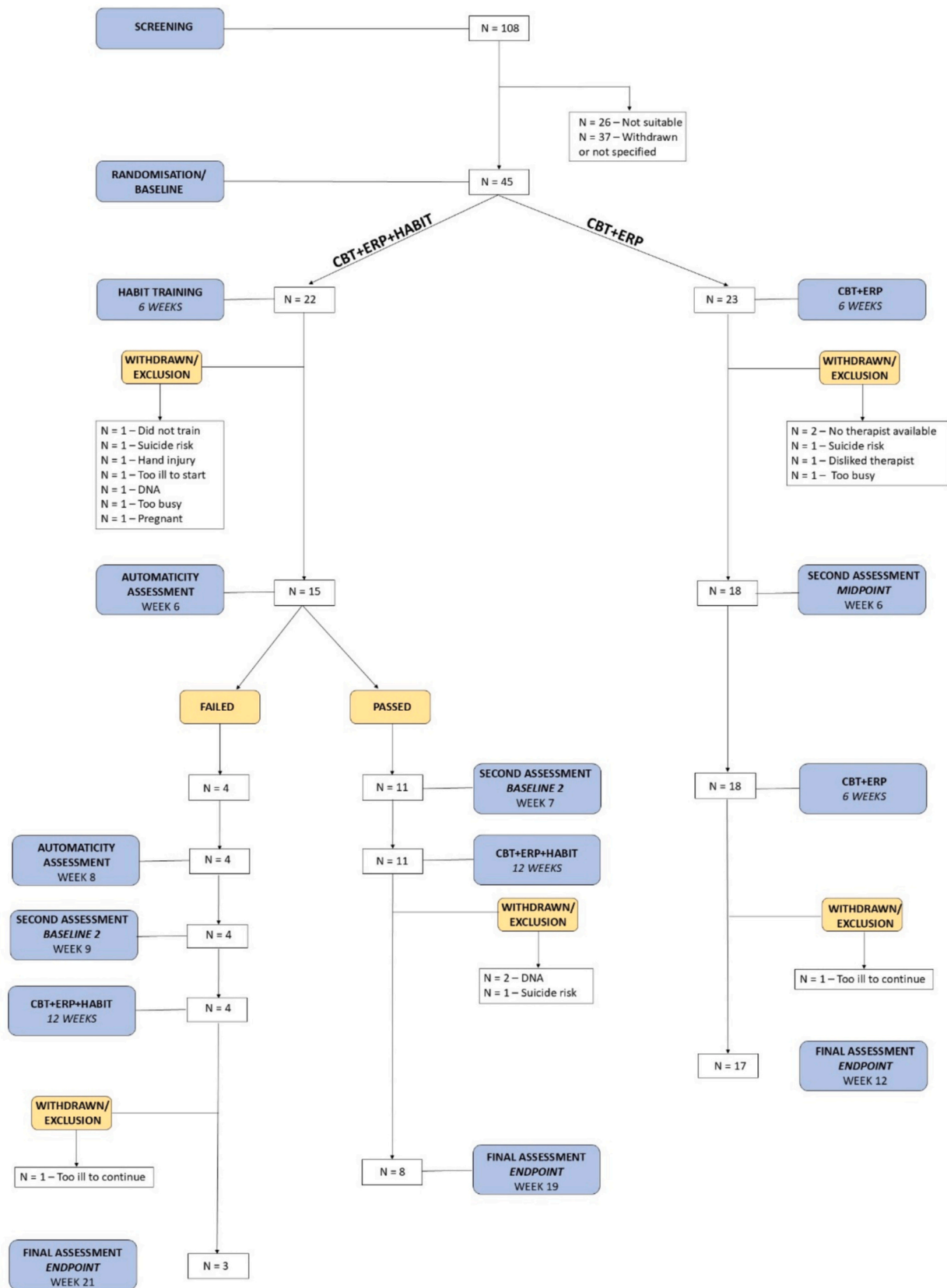


Fig. 2. Study flowchart.
DNA: Did not attend.

Table 1

Baseline demographic and clinical characteristics (means \pm standard deviations) of participants randomised to habit augmented cognitive behavioural therapy with exposure and response prevention vs cognitive behavioural therapy with exposure and response prevention.

| | CBT + ERP + Habit (N = 22) | CBT + ERP (N = 23) | $t^{a,b}$ | df | p |
|------------------------------------|----------------------------------|--------------------------|-----------------|----|------|
| Sex (male/ female) ^b | 8/14 | 6/17 | $\chi^2 = 0.55$ | 1 | 0.46 |
| Age | 34.73(10.6) | (12.1) 26.87 | -1.4 | 43 | 0.16 |
| YBOCS | 26.91(4.2) | (5.2) | 0.03 | 43 | 0.98 |
| MADRS | 15.8(9.4) | 18.1(9.7) | -0.81 | 43 | 0.42 |
| IUS | 44.45(7.5) | 42.9(7.1) | 0.71 | 43 | 0.48 |
| STAI-State ^a | 48.5(14.6) | (11.8) 20.9 | 241.000 | 42 | 1.00 |
| SDS | 19.09(6.05) | (5.65) 105.7 | -1.02 | 43 | 0.31 |
| IQ | 107.9(9.01) | (8.05) | 0.8 | 39 | 0.42 |
| Unmedicated ^b | 5 | 6 | $\chi^2 = 0.07$ | 1 | 0.79 |
| SRI monotherapy ^b | 11 | 12 | $\chi^2 = 0.02$ | 1 | 0.88 |
| SRI augmented ^b | 6 | 5 | $\chi^2 = 0.19$ | 1 | 0.67 |

^a Mann-Whitney U test reported as the t statistic. ^bChi-square test reported instead of the t statistic. All other t statistics reported the Student's t -test. Effect sizes reported as z scores for analyses using the Mann-Whitney U test. Y-BOCS: Yale-Brown obsessive-compulsive scale; MADRS: Montgomery-Åsberg Depression Rating Scale; IUS: Intolerance of Uncertainty Scale; STAI: The State-Trait Anxiety Inventory; SDS: Sheehan Disability Scale; SRI: Serotonin Reuptake Inhibitor.

four (26.7%) discontinued prematurely, two of whom withdrew owing to clinical worsening. Similarly, of the 23 participants starting CBT + ERP therapy, six (26.0%) discontinued therapy prematurely, two of whom withdrew owing to clinical worsening.

At the final endpoint of the study, those participants completing the CBT + ERP + Habit therapy arm ($N = 11$) were administered a self-report questionnaire comprising four items, enquiring how tolerable, acceptable, and impactful they thought augmenting CBT + ERP with a non-pathological habit was, and to what extent they followed the required training. Each item was rated on a Likert scale ranging from strongly disagree to strongly agree. Seven participants completed the questionnaire. Results indicated that six out of seven somewhat agreed, agreed, or strongly agreed that the habit technique was tolerable and acceptable, whilst five out of seven somewhat agreed, agreed, or strongly agreed that the technique had positively impacted their compulsions (see Fig. 2 in the supplementary materials).

3.4.2. Clinical Outcomes– ITT analysis

A comparison of the clinical outcomes in the CBT + ERP + Habit versus CBT + ERP arms are shown in Fig. 3. Importantly, because of the improvements made during habit training, at the pre-therapy baseline

Table 2

Pre-post habit training: Paired-sample t -tests of clinical outcomes in 22 participants randomised to habit augmented cognitive behavioural therapy with exposure and response prevention vs cognitive behavioural therapy with exposure and response prevention (intent-to-treat analysis).

| Scale | Pre-training M(SD) | Post-training M(SD) | Mean difference | 95% CI Pre-training | 95% CI Post-training | t^a | d | p |
|--------------------------------|--------------------|---------------------|-----------------|---------------------|----------------------|--------------|------------|--------------|
| Total YBOCS ^a | 26.9(4.2) | 24.0(6.0) | 2.9 | 28.8–25.0 | 26.7–21.3 | $W = 71.000$ | $z = 2.5$ | 0.013 |
| YBOCS Obsessions ^a | 13.0(2.5) | 11.6(2.9) | 1.45 | 14.1–11.9 | 12.9–10.3 | $W = 63.000$ | $z = 2.67$ | 0.008 |
| YBOCS Compulsions ^a | 13.9(2.3) | 12.4(3.5) | 1.45 | 14.9–12.8 | 14.0–10.8 | $W = 90.000$ | $z = 2.35$ | 0.02 |
| MADRS ^a | 15.8(9.4) | 15.0(8.3) | 0.8 | 19.9–11.6 | 18.7–11.4 | $W = 40.500$ | $z = 0.67$ | 0.53 |
| IUS ^a | 44.4(7.5) | 42.9(8.3) | 1.5 | 47.8–41.1 | 46.6–39.2 | $W = 74.000$ | $z = 1.35$ | 0.19 |
| SDS ^a | 19.1(6.1) | 16.5(7.7) | 2.6 | 21.8–16.4 | 19.9–13.1 | $W = 87.500$ | $z = 1.56$ | 0.12 |
| STAI-S ^a | 48.5(14.6) | 46.5(13.1) | 2.0 | 55.1–41.8 | 52.3–40.7 | $W = 57.500$ | $z = 0.84$ | 0.42 |

^a Wilcoxon signed-rank test reported as the t statistic. Effect sizes reported as z scores for analyses using the Wilcoxon signed-rank test. Y-BOCS: Yale-Brown obsessive-compulsive scale; MADRS: Montgomery-Åsberg Depression Rating Scale; IUS: Intolerance of Uncertainty Scale; STAI: State-Trait Anxiety Inventory; SDS: Sheehan Disability Scale; M: Mean; SD: Standard-deviation; CI: Confidence Interval.

the mean scores of most variables in those in the habit-augmented arm were numerically lower than the mean baseline scores for those in the CBT + ERP control. In the case of Y-BOCS, the mean baseline score in the CBT + ERP + Habit arm was reduced to 24 (SD = 6), compared to 26.9 (SD = 5.2) in the CBT + ERP arm. However, only the SDS scores were significantly lower for the CBT + ERP + Habit arm versus the control arm at pre-therapy baseline ($t = -2.17$, $d = -0.65$, $p = .035$).

There were no between-group differences in any change in clinical rating during the therapy phase. Both arms showed significant 'within-group' improvements from pre-therapy baseline to endpoint on the primary outcome, the Y-BOCS (CBT + ERP + Habit mean difference = 3.1, $p < .05$; CBT + ERP mean difference = 6.6, $p < .001$) and on the IUS-12. As a result, at the study endpoint, the mean total Y-BOCS scores in each arm were comparable (20.9 (SD = 8.9) versus 20.1 (SD = 6.6)). During the therapy phase, only the CBT with ERP group showed a significant reduction on Y-BOCS subscales, MADRS, and SDS scores (Table 3). Significant improvements from baseline in the Y-BOCS and MADRS were also seen at the 6-week midpoint in the CBT + ERP group (see Table 1 in the supplementary materials). No significant changes were found for anxiety scores from baseline to the end of therapy in either arm.

3.5. Adverse events

No serious adverse events (AE) were reported. Only 10 out of the 45 participants (CBT + ERP + Habit = 3; CBT + ERP = 7, $\chi^2 = 1.84$, $p = .17$) reported any adverse event, which are depicted in Table 4. AEs were noted at each rating point they were mentioned, hence the same participant may have produced multiple reports of the same AE over the duration of the study. Overall, there were 56 reports of adverse events, with participants in the CBT + ERP arm reporting 42 of them (75%). The most common AEs included anxiety, low mood, headache, and nausea. A rate ratio (RR) analysis was conducted to check for statistical differences between rates of AE reporting in both groups. A statistically greater number of AEs were reported for the CBT + ERP arm (RR = 2.87, LogRR = 1.054, $z = 3.42$, $p < .001$).

4. Discussion

In the first of its kind, this naturalistic, randomised clinical trial aimed to investigate the feasibility and effects of augmenting standard CBT and ERP with a non-pathological habit and components of habit reversal therapy (HRT). Our results corroborated our first hypothesis that habit-augmented CBT + ERP is acceptable, tolerable, and feasible to apply in a clinical environment. We did not prove our second hypothesis that the experimental treatment would be superior in terms of efficacy and tolerability than optimal standard treatment for reasons discussed in more detail below.

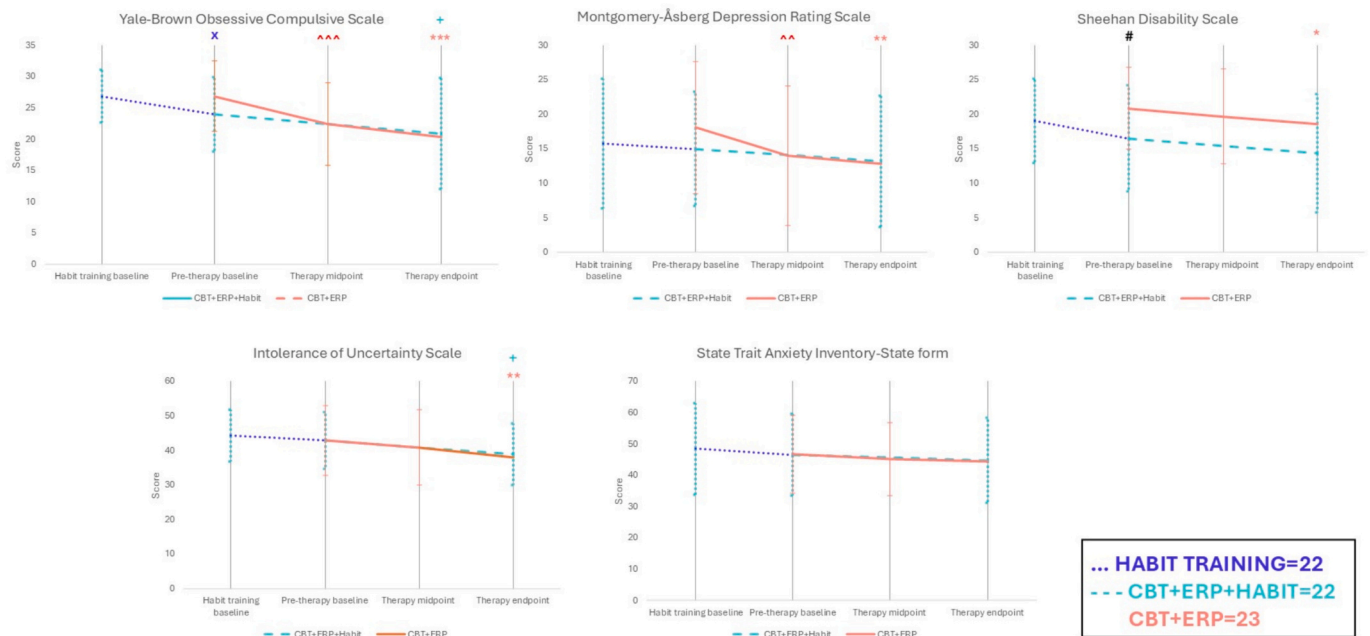


Fig. 3. Pre-to-post intervention clinical outcomes during the initial habit training phase and during the randomisation phase involving habit augmented cognitive behavioural therapy with exposure and response prevention vs cognitive behavioural therapy with exposure and response prevention (intent-to-treat analysis). CBT: Cognitive-Behavioural Therapy; ERP: Exposure and Response Prevention. Timelines: Habit training: week 0-week 6 or 8 for habit augmented arm only. Pre-therapy baseline: week 6 or 8 for CBT + ERP + Habit (after habit training) and week 0 for CBT + ERP group. Therapy midpoint: week 6 for CBT + ERP group only. Therapy endpoint: week 19 or 21 for CBT + ERP + Habit arm and week 12 for CBT + ERP arm. **Please note:** there is no therapy midpoint for the CBT + ERP + Habit group.

* $p < .05$; ** $p < .01$; *** $p < .001$. Dotted lines indicate habit training phase. ^x indicates significant within-group changes during the habit-training phase. # indicates significant between-group differences at the pre-therapy baseline. + indicates significant within-group changes from pre-therapy baseline to therapy endpoint in the (CBT + ERP + Habit) arm. ^ indicates significant within-group changes from pre-therapy baseline to therapy midpoint in the (CBT + ERP) arm. * indicates significant within-group changes from pre-therapy baseline to therapy endpoint in the (CBT + ERP) arm. Unbroken vertical lines indicate standard deviations for the CBT + ERP group. Broken vertical lines indicate standard deviations for the CBT + ERP + Habit group.

Table 3

Comparison of clinical outcomes in those randomised to habit augmented cognitive behavioural therapy with exposure and response prevention vs cognitive behavioural therapy with exposure and response prevention (intent-to-treat analysis).

| Scale | Pre-therapy baseline M(SD) | Therapy endpoint M(SD) | Mean difference | 95% CI Baseline | 95% CI Endpoint | t^a | d | p | |
|-------------------------------|--------------------------------|------------------------|-----------------|-----------------|-----------------|-----------|-------------|----------|------------------|
| CBT + ERP + Habit (N = 22) | Total YBOCS ^a | 24(6.0) | 20.9(8.9) | 3.1 | 26.7–21.3 | 24.9–17.0 | W = 55.500 | z = 2 | 0.05 |
| | YBOCS_Obsessions ^a | 11.6(2.9) | 10.1(4.2) | 1.4 | 12.9–10.3 | 12.0–8.3 | W = 55.000 | z = 1.96 | 0.055 |
| | YBOCS_Compulsions ^a | 12.4(3.5) | 10.8(5.0) | 1.6 | 14.0–10.8 | 13.0–8.6 | W = 52.000 | z = 1.69 | 0.099 |
| | MADRS ^a | 15.0(8.3) | 13.2(9.5) | 1.8 | 18.7–11.4 | 17.4–9.0 | W = 42.500 | z = 1.53 | 0.14 |
| | IUS ^a | 42.9(8.3) | 38.9(9.0) | 4.0 | 46.6–39.2 | 43.0–34.9 | W = 60.000 | z = 2.4 | 0.02 |
| | SDS ^a | 16.5(7.7) | 14.4(8.6) | 2.1 | 19.9–13.1 | 18.3–10.6 | W = 49.000 | z = 1.42 | 0.17 |
| | STAI-S ^a | 46.5(13.1) | 44.7(13.6) | 1.8 | 52.3–40.7 | 50.7–38.7 | W = 46.000 | z = 1.16 | 0.26 |
| CBT + ERP (N = 23) | Total YBOCS ^a | 26.9(5.2) | 20.3(6.6) | 6.6 | 29.1–24.6 | 23.1–17.4 | W = 169.500 | z = 3.7 | <0.001 |
| | YBOCS_Obsessions | 13.3(2.8) | 10.0(3.2) | 3.3 | 14.8–12.0 | 11.4–8.6 | W = 4.58 | z = 0.95 | <0.001 |
| | YBOCS_Compulsions ^a | 13.6(2.8) | 10.2(3.6) | 3.4 | 14.8–12.4 | 11.8–8.7 | W = 153.000 | z = 3.62 | <0.001 |
| | MADRS | 18.1(9.7) | 12.9(10.1) | 5.2 | 22.3–13.9 | 17.3–8.5 | W = 3.01 | z = 0.63 | 0.006 |
| | IUS ^a | 42.9(7.1) | 38.0(11.0) | 4.9 | 46.0–39.8 | 42.8–33.2 | W = 131.000 | z = 2.6 | 0.01 |
| | SDS ^a | 20.9(5.6) | 18.6(6.9) | 2.3 | 23.3–18.4 | 21.6–15.6 | W = 77.000 | z = 2.2 | 0.03 |
| | STAI-S | 46.7(11.8) | 44.4(11.6) | 2.3 | 51.9–41.6 | 49.5–39.4 | W = 0.83 | z = 1.04 | 0.40 |

^a Wilcoxon signed-rank test reported as the t statistic. All other t statistics reported the Student's t -test. Effect sizes reported as z scores for analyses using the Wilcoxon signed-rank test. Y-BOCS: Yale-Brown obsessive-compulsive scale; MADRS: Montgomery-Åsberg Depression Rating Scale; IUS: Intolerance of Uncertainty Scale; STAI: The State-Trait Anxiety Inventory; SDS: Sheehan Disability Scale; M: Mean; SD: Standard-deviation; CI: Confidence Interval.

Table 4
Adverse events.

| Reported adverse event | Participants CBT + ERP + HABIT n (%) | Participants CBT + ERP n (%) | Number of reports for CBT + ERP + HABIT | Number of reports for CBT + ERP |
|--|--------------------------------------|------------------------------|---|---------------------------------|
| Anxiety | 2 (9.1) | 3 (13.04) | 5 | 7 |
| Low mood | 1 (4.5) | 3 (13.04) | 1 | 7 |
| Headache | 0 (0.0) | 2 (8.7) | 0 | 5 |
| Nausea | 0 (0.0) | 2 (8.7) | 0 | 4 |
| Tiredness | 0 (0.0) | 1 (4.3) | 0 | 2 |
| Frustration | 1 (4.5) | 1 (4.3) | 1 | 1 |
| Suicidal thoughts | 1 (4.5) | 0 (0.0) | 1 | 0 |
| Chest pressure | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Sore eyes | 0 (0.0) | 1 (4.3) | 0 | 2 |
| Disturbed sleep | 1 (4.5) | 0 (0.0) | 2 | 0 |
| Body checking | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Compulsive behaviour | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Intrusive images | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Body pain due to ERP | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Sweating | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Lack of concentration | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Weight loss | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Guilt | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Self-harm | 1 (4.5) | 0 (0.0) | 1 | 0 |
| Fainting | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Awareness of new symptoms | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Confusion on how to deal with symptoms | 0 (0.0) | 1 (4.3) | 0 | 1 |
| Fear of symptoms increasing from treatment | 1 (4.5) | 0 (0.0) | 1 | 0 |
| Total participants affected by any AE = 10 | 3 (13.63) | 7 (30.43) | | |
| Total number of AE reports = 56 | | | 14 (25.0) | 42 (75.0) |

Please note: The total number of participants reporting any adverse event (AE) does not reflect the sum of participants reporting any AE in the group columns, as each patient could report more than one AE. Percentages reflect the proportion of individuals reporting AE in comparison with the total number of participants in each group (i.e. CBT + ERP + Habit = 22; CBT + ERP = 23). Percentages following number of AE reports were calculated based on the total number of reports (i.e. 14/56 and 42/56).

4.1. Feasibility of recruitment of participants (acceptability)

Recruitment of participants for this trial involved liaison with primary and secondary care services (IAPT and CMHS), who referred treatment-seeking individuals diagnosed with OCD to the study. In total, 108 participants were screened for eligibility, with 45 forming the final sample. Those numbers indicate both the willingness of staff to refer participants and the challenges typically experienced when recruiting participants with OCD for even non-placebo trials, as fewer than 50% (circa 42%) of the potentially eligible participants engaged in the study. Future research involving focus group work, and collaborations with lived experience advisory groups (LEAGs) and consumer charities, could be expected to improve recruitment and strengthen research feasibility in the OCD population.

4.2. Feasibility of recruitment and training of therapy staff

Recruitment of staff was heavily reliant on supportive relationships

with NHS line managers, since they were working voluntarily alongside their work schedule. The weekly structured and consistent supervision process, involving monitoring of protocol adherence and troubleshooting arising clinical or research issues, arguably facilitated therapist engagement and adherence to the research framework. Our results indicate that staff training on the study protocol and supervision was feasible, as no therapists dropped out during the study and supervision was rigorously adhered to, suggesting that the habit augmentation therapy was adequately applied by the staff.

4.3. Tolerability (premature discontinuation and adverse effects)

A relatively high rate of premature discontinuation (7/22 = 31.8%) took place in the habit training phase, which contributed to the numerically (but statistically non-significant) higher rate of discontinuation seen across the full duration of the trial in the CBT + ERP + Habit arm (50% versus 26%). Of note, the lack of statistical difference could be a result of the low sample sizes. In contrast, the rates of premature discontinuation across the therapy phases were roughly equivalent in both arms (26.7% versus 26%), suggesting that the habit augmented therapy was, of itself, acceptable. In fact, seven out of the 11 (64%) participants who dropped out in the habit-augmented group did so in the initial, 'training' phase of the trial. Some participants may have found the extended period of habit training unacceptable, possibly because of the novelty of the approach. Others may have felt disappointment that they were obviously not randomised to receive active therapy from the start and/or difficulties committing to a prolonged exercise phase without expectation of an obvious therapeutic gain. Of note, five out of the six participants who dropped out in the CBT + ERP arm did so in the first six weeks of treatment. These findings of discontinuations tending to occur early in the study are consistent with other studies [62] and may simply reflect general difficulties in initial engagement and adherence. Nevertheless, careful explanation of the rationale for habit training would seem to be important to optimise engagement in future studies of habit reversal therapies in OCD. It is noteworthy that one participant had to be withdrawn from habit training due to pain in the hands when being taught how to play the app. This is especially relevant when selecting participants to undergo treatments that require physical movement, as not everyone will be able to participate in them.

Adverse events were infrequently reported in both arms. There were no serious adverse events. We did not apply a standardised measure of severity, but none were judged by the treating clinician to be severe and only one participant (in the CBT + ERP arm) required clinical intervention (for an episode of fainting and anxiety). Adverse event information, albeit rarely collected in trials of psychological therapies, is essential for understanding treatment adherence, as associations between ERP and physiological responses have been reported [63,64]. Indeed, our results add evidence to these findings, with the CBT + ERP arm reporting a significantly greater adverse events load ($p < .001$), particularly related to low mood and somatic symptoms, such as nausea and headaches, consistent with research findings that individuals with OCD over-monitor their internal bodily signals, such as heart beats [65]. Although impossible to state with certainty at this point, owing to the small size of the study, and the fact that AE monitoring was performed by unblinded therapists and therefore subject to potential bias, it is possible that experimentally introducing a habit as a competing response to compulsions during ERP shielded individuals against some of the distressing effects induced by ERP. This is potentially clinically relevant, considering the difficulties participants report in tolerating ERP for OCD and the impact of failed treatments on prognosis and illness progression [62]. Interestingly, anxiety as measured on the STAI-state did not differ between the arms, which could potentially indicate that anxiety in OCD, including during ERP, is experienced differently as bodily sensations. An alternative possibility is that participants at a higher risk of adverse events discontinued treatment during the habit training phase, leaving fewer individuals in the experimental condition

that would report them. Although research is not in agreement concerning the relationship between adverse events and dropouts, evidence suggests that the former can trigger the latter [66]. In any case, the mechanism behind the adverse events differences remains a subject for a future study.

4.4. Effectiveness of habit training

Despite not receiving any psychological support, and notwithstanding the notable dropout rate during this phase, participants' Y-BOCS scores improved significantly during habit-training - an unexpected finding, which remains to be further elucidated. On the ITT analysis, the mean post-baseline improvement on the total Y-BOCS reached 2.9 points (SE = 1.04; 10.8%). When those who completed habit training were analysed separately, the mean total Y-BOCS improvement increased to 5.4 points (SE = 1.76; 20.85%), which would be considered clinically relevant, although not reaching the magnitude of a clinical response (usually represented by a 25% improvement on the Y-BOCS) [67]. Investigation of the Y-BOCS subscales showed numerical improvement across both obsessions and compulsions, emphasising the importance of investigating the mechanism of this effect in more detail.

Intriguingly, similar results have been reported by Banca et al. (2024) [10], who conducted a study of motor habit learning with the same mobile application in a different sample of participants with OCD and matched controls and found improvements on Y-BOCS occurring during training alone. Moreover, comparing to those who did not improve, those who improved on Y-BOCS during habit-training were statistically more likely to prefer to keep performing the app sequences when offered the possibility to perform different sequences in a subsequent behavioural test. The authors explained this as a tendency to attribute an intrinsic value to completing familiar action sequences. Other research shows that performing complex behaviours can provide a reward in itself, as completing a sequence of rigid motor actions may satisfy a natural need for order [68]. These observations may explain the positive effect of habit training per se, i.e. working to reduce OCD symptoms by activating reward mechanisms that compete with compulsive urges, and which may work best in a subset of OCD participants with a preference for familiarity and habitual tendencies.

It is however critically important to note that the participants were aware of which treatment they were allocated to and that there was no control intervention during the habit training phase in both this and Banca's studies, which means that we cannot be certain that habit training is responsible for the clinical improvement. Improvement may result instead from other non-specific factors such as the attention and support received by the researcher during training, expectancy associated with a novel intervention, the obligation to complete a task daily, which could boost routine and provide a sense of achievement and self-efficacy, amongst others. Future controlled studies of habit training, designed to disentangle those factors are, thus, indicated.

4.5. Effectiveness of habit augmented CBT + ERP

Our study was the first to test habit augmented CBT + ERP against a control. It was designed to test feasibility and explore signals that might indicate efficacy but was not powered to detect statistically significant between-arm differences. Augmenting CBT + ERP with a competing habit was not only feasible, but the experimental treatment yielded comparable improvements in the primary outcome - the Y-BOCS, and in intolerance of uncertainty, to CBT + ERP, which is considered the optimal form of psychotherapy for OCD. Moreover, participants reported fewer adverse events. These findings hint at a potential tolerability advantage of the habit augmented CBT arm, at least for those who manage to complete the habit training and start therapy, thereby potentially addressing aspects of the tolerability issues that 'haunt' CBT + ERP [20,27].

The relative reduction in adverse events during habit augmented

therapy could reflect a sense of relief and urge attenuation provided by the habit, especially during exposure when distress levels are expected to be high, and the importance of addressing regulation of sensorimotor activity in OCD [69]. Importantly, we conducted a conservative, ITT analysis, which is likely to have masked treatment effects. Consequently, we performed an exploratory analysis of those completing either treatment arm to identify any subtle differences in outcome that may have been obscured by the ITT analysis. This completer analysis (CBT + ERP + Habit (N = 11), CBT + ERP (N = 17)) revealed that the clinical improvement during the study, from first baseline to endpoint, was numerically larger for the habit-augmented group on the Y-BOCS compulsion subscale (i.e. mean difference = 6(SE = 1.23)) compared to the control group (mean difference = 4.6(SE = 0.76)), signalling a possible preferential effect of the experimental treatment on the behavioural aspects of OCD. Nevertheless, those differences were not significant between-arms. Participants in both arms achieved comparable Y-BOCS scores at the study endpoint. In addition, the completer analysis revealed that disability (SDS) scores were significantly lower at endpoint in the habit augmented arm when compared to the control condition ($p = .006$), along with a marginally significant within-group improvement during habit training ($p = .075$), suggesting that the ITT analyses were likely to have been affected by the substantial dropout rate seen in the habit training phase of experimental arm. Possibly, this dropout rate could be reduced, and the overall success of the habit-augmented treatment amplified, by selecting participants with a preference for familiarity [10].

Questions relating to the mechanisms of action of introducing the habit remain. For instance, it would be important to understand if there is a specific profile of participants who could benefit more from the habit augmentation compared to CBT + ERP alone. Based on Banca et al. (2024) findings [10], patients with higher habitual tendencies seem to benefit more from this type of therapy. Of particular significance, due to the feasibility nature of this study and small sample size, we did not control for compulsion subtypes in this trial. The original research by Azrin and Nunn (1973) in relation to habit disorders suggests that competing responses should be dissimilar to the ones being targeted, constituting physically incompatible behaviours. In this study, all participants used the same competing response, but it is unclear whether this response was fully incompatible with each participant's compulsion. Although there is evidence for similar competing responses being employed in treatment [70,71] and for a general neural domain of compulsions, whereby similar brain areas are active regardless of behavioural presentation [72], we cannot exclude the possibility that the competing habit was not enabling the performance of a compulsion. Nevertheless, the magnitude of the reduction in Y-BOCS scores seen in the experimental group confers a degree of confidence that this was not the case. Future research would benefit from testing this hypothesis and tailoring the competing response to particular symptom profiles. Depression scores were not improved in the CBT + ERP + Habit arm. This may be simply explained by the relatively lower levels of depression in the habit augmented sample. Nor was there any reduction in anxiety scores, suggesting that the improvement in OCD symptoms seen in this arm was not a result of improvement in mood or anxiety. These findings suggest that habit-augmented therapy may work via behavioural and not emotional changes and signal a preferential clinical role for habit augmented CBT + ERP in patients with OCD who are either not seriously depressed or are receiving another treatment for depression.

4.6. Methodological critique

The study benefitted from taking place under randomised controlled conditions with blinded outcomes ratings. Participants with moderately severe OCD, representing a typical treatment seeking population, were well-matched across each treatment arm at baseline. The key limitations in our design were the lack of a behavioural control and of adverse event monitoring during the preliminary habit training phase, which would

have provided important additional information regarding its efficacy and tolerability. Our results show that participants experienced significant improvements during habit training, but several dropped out prematurely. Future studies should investigate habit training under controlled conditions, to establish those factors affecting adherence to habit-training and its efficacy.

Nevertheless, 12 weeks of CBT + ERP augmented with habit was found to be feasible, tolerable, and acceptable to participants, and therapists were able to competently deliver the new form of therapy within a regular health service setting. Furthermore, the experimental treatment yielded promising clinical outcomes compared to the 'gold-standard' CBT + ERP control, though no between-group differences were found at any timepoints on the primary analysis.

It is important to note that this was a small-scale feasibility study, not powered to determine equivalence and so our understanding of the efficacy of habit-reversal components in the treatment of OCD remains incomplete. Moreover, the majority of participants were female. Whereas the sex balance in the study cohort was broadly representative of the clinical setting, as fewer males were tested, we have even less certainty about outcomes in the male clinical population. Another limitation applies to the self-report data on tolerability, efficacy, and impact of therapy, which was solely gathered for those in the CBT + ERP + Habit arm who completed the trial. Given the difficulties some participants found adhering to habit training and the relatively poor tolerability of CBT + ERP, in future work it would be important to assess how participants found these additional aspects of the intervention.

Furthermore, whilst the therapists in the trial suggested that introducing the habit during exposure was feasible and tolerable, no objective measures (i.e. online monitoring of app usage) was collected during the treatment stage, hence no firm conclusions can be drawn about the extent to which the habit was actually used, either as a contingent response following a compulsive urge, or as a non-contingent action, during therapy sessions and homework. This is particularly important, as it is possible that improvement seen in the habit arm was due to non-engagement in the compulsion, akin to classic ERP. Similarly, participants in the CBT + ERP arm may have engaged in competing responses, such as distraction, although this strategy is not recommended for OCD and has been associated with detrimental outcomes [73]. Future studies should employ objective measures, such as digital adherence monitoring, and aim to collect adverse events and self-report data from all those starting habit training and CBT + ERP.

As a requirement of the trial was to achieve automaticity in performing a newly learnt, competing habit, individuals in the habit augmented arm participated in the study for an extra 7–9 weeks than the control arm, during which period they were contacted by the researcher if training days were missed. Thus, the trial was potentially biased in favour of those completing the CBT + ERP + Habit arm, who had a longer time-period to improve. Indeed, habit training did result in symptom improvement, leading to lower baseline scores in the CBT + ERP + Habit group prior to starting therapy. We applied an ITT analysis in an attempt to control for this bias. On the other hand, participants in the experimental arm had already experienced a significant decrease in Y-BOCS scores before their therapy started. Thus, they started therapy with lower Y-BOCS scores and there was potentially less scope for therapy-related improvement over the subsequent weeks in the habit augmented arm.

Finally, it is important to note that much of the trial occurred during the Coronavirus pandemic, with treatment and research sessions having to adapt from in-person to remote based. Despite these circumstances, the work was protected by the hospital trust as a priority, and the research was never interrupted. No participants or therapists withdrew from the study due to the pandemic.

5. Future directions

Several unanswered questions remain. To what extent do

participants benefit from habit-augmented CBT + ERP, above and beyond standard treatment, and how does it work mechanistically? Is it necessary for the new habit to be automatic or would any competing response be effective? How important is habit training for clinical improvement? How much training time is necessary? Would Y-BOCS scores have differed had they been measured after 6 weeks of training, when automaticity failed for some, as opposed to eight weeks?

Albeit impossible to ascertain in the current study, one could argue that habit training and automaticity are indeed necessary to create responses operating via S-R associations, rather than the action-outcome (A-O) association maintained by negative reinforcement seen in compulsions (i.e. urge > compulsion > relief) [2,74,75]. Indeed, a recent study proposes that, in order to break a habit, the weakening of the S-R association and the formation of a competing one is necessary [75], which would corroborate our choice for introducing a trained motor sequence. It does seem that habit-augmented ERP is beneficial in the treatment of OCD by integrating an extra step in the classic approach, namely response re-engagement. Since both techniques emphasise suppression of the prepotent motor response, the habit-augmented ERP could be interpreted as a continuation of ERP.

Our study was not powered to show significant between-arm differences and so a larger study is needed to confirm some of the exploratory signals. Future studies should expand on the current trial using a design that controls for the habit training as well as the therapy elements. Specifically, it would be important to confirm if there are beneficial aspects of learning and performing a competing habit, and if so whether this relates to automaticity or simply the performance of any repeated motor action. For instance, future research could introduce a control group performing non-automatic and stereotypical hand movements alongside a relaxation group that would perform no movements at all. It would also be important to identify if the participants that benefit from HRT components are indeed those with higher habitual tendencies, which could be relatively easily measured using a simple behavioural task and inventories assessing habitual tendencies [10].

It is worth noting that this study comes at a time when motor abnormalities in psychiatric disorders are beginning to be addressed. The National Institute for Mental Health (NIMH), in its Research Domain Criteria (RDoC) framework matrix [76–79], has recently proposed the incorporation of a new *Sensorimotor Systems* domain, composed of sub-constructs such as *Motor Actions*, *Agency and Ownership* and *Habits* [80–82], all of great relevance to OCD. Stratification of patients to different treatment approaches based on motor abnormalities is a future possibility that could improve treatment outcomes of this highly debilitating condition.

6. Conclusions

Despite methodological confounds, including small sample-size, and a conservative data-analysis approach, the first blind-rated randomised clinical trial of HRT components in OCD has produced encouraging results. Augmentation of CBT + ERP with habit was feasible, acceptable, and tolerable, yielding similar efficacy to standard CBT + ERP and potentially fewer adverse events. Novel behavioural interventions such as habit augmented ERP extend beyond traditional cognitive approaches and offer promise for moving toward a personalised treatment approach, based on measurable behavioural characteristics [6,7,83,84], meriting further investigation in larger, well designed clinical trials.

CRedit authorship contribution statement

Ana Maria Frota Lisboa Pereira de Souza: Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Davis Mpavaenda:** Writing – original draft, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Paula Banca:** Writing – original draft, Supervision, Resources, Methodology, Investigation, Conceptualization. **David**

Wellsted: Supervision, Methodology, Formal analysis. **Janine Hopkins:** Project administration. **Aleya A. Marzuki:** Investigation. **Monika Lee:** Investigation. **Evmorfia Karafylli:** Investigation. **Olga Bardsley:** Investigation. **Sabina Mazoruk:** Investigation. **Stefanie Skalecki:** Investigation. **Shanti Boodhun:** Investigation. **Hannah Mendoza-Wolfson:** Investigation. **Claire Crispin:** Investigation. **Rebecca Alonftis:** Investigation. **Deela Monji-Patel:** Investigation. **Eduardo Cinosi:** Investigation. **Luca Pellegrini:** Investigation. **Arun Enara:** Investigation. **Seema Panjwani:** Investigation. **Maham Riaz:** Investigation. **Stacey Oliver-Singleton:** Investigation. **Trevor W. Robbins:** Writing – original draft, Supervision, Methodology, Conceptualization. **Naomi A. Fineberg:** Writing – original draft, Supervision, Methodology, Investigation, Formal analysis, Conceptualization.

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Appendix A. Supplementary data

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