RESEARCH PAPER

Factors influencing the efficacy of an online behavioural intervention for children and young people with tics: Process evaluation of a randomised controlled trial[☆]

Kareem Khan[a,b,*], Chris Hollis[a,b,c], Charlotte L. Hall[a,b], E. Bethan. Davies[a,b], Elizabeth Murray[d], Per Andrén[e], David Mataix-Cols[e], Tara Murphy[f,g,h], Cris Glazebrook[a,b]

[a] *Mental Health and Clinical Neurosciences, School of Medicine, University of Nottingham, Nottingham, United Kingdom*
[b] *NIHR MindTech Medtech Co-operative, Mental Health and Clinical Neurosciences, Institute of Mental Health, University of Nottingham, Nottingham, United Kingdom*
[c] *NIHR Nottingham Biomedical Research Centre, Mental Health and Clinical Neurosciences, Institute of Mental Health, University of Nottingham, Nottingham, United Kingdom*
[d] *Research Department of Primary Care and Population Health, University College London, London, United Kingdom*
[e] *Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm Health Care Services, Region Stockholm, Stockholm, Sweden*
[f] *Tic Disorder Clinic, Great Ormond Street Hospital for Children NHS Foundation Trust, Great Ormond Street, London, United Kingdom*
[g] *UCL Great Ormond Street Institute of Child Health (ICH), 30 Guilford Street, London WC1N 1EH, United Kingdom*
[h] *Great Ormond Street Hospital for Children NHS Trust, Great Ormond Street, London WC1N 3JH, United Kingdom*

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Abstract The Online Remote Behavioural Intervention for Tics (ORBIT) trial found that an internet-delivered, therapist-supported, and parent-assisted Exposure and Response Prevention (ERP) intervention reduced tic severity and improved clinical outcomes. This process evaluation aimed to explore mechanisms of impact and factors influencing efficacy. Participants were 112 children with a tic disorder and their parents randomised to the active intervention arm of the ORBIT trial. Child engagement was assessed by usage metrics and parent engagement by chapter completion. Experiences of the digital intervention were explored by semi-structured interviews. Outcomes (3-months post randomisation) were change in tic severity and overall clinical improvement. Tic severity reduced from baseline to 3-month follow-up and 36% were rated as much improved clinically. Greater tic severity at baseline predicted reduction in tic severity. Parental engagement was the only independent predictor of clinical improvement. There were no statistically significant mediators or moderators of the relationship between level of child engagement and outcome. From the qualitative findings, child participants appreciated working together with parents on the intervention and participants found the intervention engaging. ORBIT may be an effective and acceptable intervention for children and young people with tic disorders, with parental engagement being a key factor in successful outcomes.

Introduction

Tic disorders, such as Tourette syndrome (TS) and chronic tic disorders (CTD), are highly distressing neurodevelopmental conditions, which typically commence in mid-childhood and are more common in children and young people (CYP) than in adults (Martino & Leckman, 2013). Although behavioural therapy is effective and avoids the unpleasant side effects associated with medication, access to therapy is limited due to insufficient number of specialists and uneven geographical distribution of services relative to demand (Cuenca et al., 2015). Digital health interventions (DHIs) have been shown to be effective for a range of neurodevelopmental disorders in CYP, including tic disorders, and thus offer potential to widen access to evidence based behavioural treatments (Andrén et al., 2019; Khan, Hall, Davies, Hollis, & Glazebrook, 2019). However, despite an expanding body of evidence to support the acceptability and efficacy of online therapy, uptake of DHIs into clinical practice has been disappointing (Bennion, Hardy, Moore, & Millings, 2017). Previous research has focused on intervention outcomes with little attention to the mechanisms of impact: the way in which the intervention components and participants' responses to the intervention produce change. Knowledge of how and why a DHI works increases the potential for replication across contexts (Moore et al., 2015). Furthermore, understanding mechanisms of impact is crucial for assessing core components of an intervention (e.g., ''essential ingredients''), which helps with defining the minimum therapeutic dose.

There are no studies in the tic disorder literature assessing mechanisms of impact of digital interventions, however studies of face-to-face behavioural therapy for tics have suggested that clinical factors can moderate the efficacy of behavioural treatment. Sukhodolsky et al. (2017) found that the presence of tic medication significantly moderated impact. For participants receiving ten weeks of behavioural therapy, medication status did not impact on efficacy. In contrast, participants in the psychoeducation and supportive therapy group who were receiving medication showed significantly greater tic reduction than participants not on medication. Tic phenomenology, age, gender, family functioning, treatment expectancy, and comorbidities did not moderate response to treatment. A more recent study which examined moderators of treatment outcome after adolescents with CTD received either individual or group therapy found that higher level of anxiety and a higher premonitory urge to tic favoured treatment in groups, whereas increased sensitivity and higher depression symptomology favoured individual treatment (Nissen, Parner, & Thomsen, 2019).

The Online Remote Behavioural Intervention for Tics (ORBIT) randomised controlled trial (RCT) found that a parent and therapist supported online remote behavioural intervention for CYP was associated with a significant reduction in tic severity ($d = -0.31$) and improved clinical outcomes in CYP aged 9 to 17 compared to an active psychoeducation control (Hollis et al., 2021). The intervention was based on Exposure and Response Prevention (ERP) therapy whereby participants were requested to first practise controlling all their tics for increasingly longer periods of time (response prevention), and then to deliberately provoke the premonitory urges whilst attempting not to release any tics (exposure and response prevention). All tics were targeted at the same time. Specific triggers to provoke the urge to tic were identified and used by participants, and then employed in everyday situations to improve generalisability. Information was presented in chapters, which the family (CYP and parent) were requested to work through. A therapist supported the delivery of the intervention and made contact with families each week to check progress, encourage motivation and answer questions, but did not deliver therapeutic content. The ERP intervention consisted of 10 chapters for CYP and 10 different chapters for parents, designed to be delivered over 10 weeks. The ten parent chapters focused on how best to support the child during their treatment. Therapists provided support through asynchronous contact (typically delivered via online messages

sent through the online platform) during these 10 weeks. Participants were deemed ''treatment completers'' if the first four chapters were completed (i.e. the designated minimum threshold for effective dose).

We have followed the Medical Research Council's (MRC) (2015) (Moore et al., 2015) guidelines for conducting a planned, mixed-methods, two-phase process evaluation of the ORBIT trial to explore: (Phase 1) the fidelity of delivery and the contextual factors influencing engagement with the intervention; (Phase 2) the impact of the intervention and mediators, contextual factors, and moderators of impact (Khan et al., 2020). Phase 1 showed that fidelity of delivery was high with child participants completing an average of 7.5 out of 10 chapters and 88.4% receiving the minimum effective dose of the first four chapters (Khan et al., 2021). Factor analysis was used to develop a comprehensive measure of child engagement. Parental engagement (i.e., parents' chapter completion and therapist time for parent) independently predicted child engagement in a regression analysis. Qualitative data from interviews with children and parents confirmed the importance of parental support for child engagement. However, the capacity of parental engagement to influence the association between level of child engagement and treatment outcome has not yet been examined.

The present investigation uses qualitative and quantitative data to explore the contextual factors influencing efficacy and factors moderating and mediating the relationship between level of implementation of the intervention (child engagement) and the efficacy of the intervention (reduction in tic severity and clinical improvement). This will provide insight into how and why outcomes occurred under given circumstances and what mechanisms underlie these impacts. To the best of our knowledge, the current study is the first to examine potential mediators and moderators of the efficacy of an online intervention delivered to CYP with tic disorders.

Methods

Study design

This study used a mixed-method, longitudinal design to explore the mechanisms of impact of an online, therapist supported, parent assisted ERP intervention for CYP with tics delivered via the BIP TIC platform (Andrén et al., 2019). The study used quantitative analyses to explore contextual factors, mediators and moderators of impact and qualitative analyses to illuminate those relationships in more depth.

Participants

Participants were CYP randomised to receive the active intervention ($n = 112$) and their parents. Inclusion criteria for the trial were CYP aged 9—17 years, with a Yale Global Tic Severity Scale Total Tic Severity Score (YGTSS-TTSS) of > 15, or > 10 if only motor or vocal tics were present, suggestive of moderate or severe tic disorder (TS or CTD). They also had to provide written, informed consent (parental consent for a child aged < 16 years) and have broadband internet access and regular use of a computer/smart phone (Hall et al.,

2019). From this sample, CYP ($n = 20$), and their parents ($n = 20$) participated in semi-structured interviews. Participants were purposively sampled to represent views from a range of ages, gender, ethnicity, and level of interaction with the intervention. There were six therapists in ORBIT, and all were invited to be interviewed. There were 16 participant referral sites (CAMHS and paediatric clinics) involved in the ORBIT trial and one clinician from each site was invited to participate in interviews. Four therapists and six referring clinicians agreed to participate in semi-structured interviews.

Measures

Outcomes

The primary outcome for assessing impact was the tic severity change score as measured by the YGTSS-TTSS (Leckman et al., 1989) at primary end-point (3-month post randomisation) minus the YGTSS-TTSS at baseline. The YGTSS is a valid and reliable, clinician-rated scale, which scores the severity of motor and vocal tics separately by an evaluation of the number, frequency, intensity, complexity, and interference of tics. Each domain is scored on a 0—5 scale. Two tic severity scores are given: total motor (0—25) and total vocal (0—25), which when combined give the YGTSS-TTSS (0—50). In this trial, the range of YGTSS-TTSS scores at baseline was 12 to 50. Hence, possible scores on the tic severity change measure could range from 38 (maximum possible deterioration) to −50 (maximum possible improvement in tic severity).

The secondary outcome measure used was the Clinical Global Impressions-Improvement Scale (CGI-I) (Guy & National Institute of Mental, 1976). The CGI-I consists of one item which compares the patient's condition at admission to the study (baseline) to the patient's condition having received the treatment (primary end-point). This is rated from 1 (very much improved) to 7 (very much worse). Using CGI-I to indicate response to treatment, the scale was dichotomised to define response as 'improved' or 'much improved' versus non-response as 'minimally improved', 'stayed the same', 'worse' or 'very much worse'. Both outcomes were completed by the same trained and reliable assessors blind to intervention status.

Child engagement factor score

In order to establish a comprehensive measure of child's level of engagement with the intervention, a principal components analysis with varimax (orthogonal) rotation found seven variables loaded on the engagement factor representing higher dose of intervention received: more logins, more chapters completed, more therapist time for child (SMS based support), greater total number of characters submitted to therapist within the online platform, fewer days between logins, fewer number of pages visited per login, and less telephone contact by the therapist (engagement prompts) (Khan et al., 2021).

Contextual, mediator and moderator variables

Contextual variables are those that influence level of efficacy directly whereas mediators and moderators potentially change the relationship between the level of delivery of the intervention (ie child engagement) and the efficacy

(i.e. reduction in tic severity, clinical improvement). Thus, based on previous research on behavioural therapy for tic disorders (Nissen et al., 2019; Sukhodolsky et al., 2017) and theoretical assumptions, as well as recommendations about the domains that should be included when conducting moderator and mediator analyses in paediatric RCTs (Burns, Hoagwood, & Mrazek, 1999), the following four potential mediator variables were selected: depression change (as measured on the Mood and Feelings Questionnaire [MFQ]) (Costello & Angold, 1988), anxiety change (as measured on the Spence Child Anxiety Scale [SCAS]) (Spence, 1998), treatment satisfaction (Likert scale: overall satisfaction 0—32), and treatment credibility (Likert scales: how well suited and how much better do you expect to be from treatment 0—8). Treatment satisfaction and credibility scales were constructed by the research team. The following seven potential moderator variables were selected: medication use, comorbidity, parental support (number of chapters completed), baseline tic severity (as measured on the YGTSS-TTSS), age, deprivation (as measured on the index of multiple deprivation [IMD]) (The English Indices of Deprivation 2019, 2019), and mother's level of education. Contextual variables were selected based on findings from phase 1 of the process evaluation (Khan et al., 2021) and outcomes from the exploratory correlational analyses.

Data collection

The data collection is described in detail in the process evaluation protocol (Khan et al., 2020). In brief, the data collection period was between August 2018 and January 2020. Demographic data including child's age, residence, gender, ethnicity, parental level of education, all current psychiatric diagnoses, and current medication use were collected at baseline (pre-randomisation) and clinical data including YGTSS-TTSS, MFQ, and SCAS were collected at baseline and at the primary end-point (3-months post randomisation). The CGI-I was collected at the primary end-point only. Semi-structured interviews with CYP and parent participants were conducted following completion of the intervention after the collection of data for the primary end-point. Interviews with therapists were conducted early in the study and near the end of recruitment to gain an understanding of their experience at different time points. Interviews with referring clinicians were conducted at the end of recruitment.

All interviews were conducted either face-to-face, by telephone, or via videoconferencing (WebEx or Skype). Younger children were interviewed together with their parents, while older children were interviewed separately.

Statistical analysis

Data were tested for normality using the Kolmogorov—Smirnov test. A repeated measures ANOVA was initially run to determine an effect on tic severity over time. Effect size of the intervention was calculated using Cohen's d (Cohen, 2013). Spearman correlations were used to analyse relationships between the outcome variables (YGTSS-TTSS change and CGI-I) and all contextual, mediator, and moderator variables. This was to establish whether a relationship between the variables exists prior to the next stage of analysis. Contextual variables were examined by simple correlations and in a multiple linear regression model. Mediator analyses were conducted using the bootstrapping indirect effects method using the PROCESS macro in SPSS (Hayes, 2009). Based on a sample size of 112 participants and with 80% power, it was estimated using Fritz and MacKinnon's (2007) simulation table that we would be able to detect at least a medium effect for each arm of the mediation (minimum sample size required = 71 participants). However, the sample size fell well short of the 462 participants required to detect a small effect for each arm of the mediation analysis with 80% power.

Moderators were examined using regression models. Each potential moderator variable was examined one by one. To formally assess the statistical significance of any observed moderation effect, a multiple linear regression model was fitted with inclusion of an interaction term between child engagement factor score and the moderator variable.

Each variable was centred prior to its inclusion in the mediator and moderator models; continuous variables were centred at their respective means, while binary variables were recoded as −0.5 and 0.5 (rather than 0 or 1). Centring refers to the subtraction of the overall mean from each observation. Therefore, each variable is ''zeroed'' at its own mean. Centring the data aids interpretation of mediator and moderator analyses and diminishes the effects of multicollinearity (Kraemer & Blasey, 2004).

Given the exploratory nature of the mediator and moderator analyses, we did not correct for multiple comparisons (Armstrong, 2014). All data used a significance level of $p < 0.05$. All statistical analyses were conducted using IBM SPSS Statistics version 27.

The qualitative data set was subjected to the framework method of analysis (Ritchie & Spencer, 1994) and the steps outlined by Gale, Heath, Cameron, Rashid, and Redwood (2013). The software package QSR NVivo 12 was used to analyse this data. Overall, the findings from the qualitative analysis were linked to relevant quantitative measures and contextual factors to assess which potential mediators and moderators may have impacted upon the mechanisms through which change occurred in an approach termed 'triangulation'.

Ethical considerations

Ethical approval for the process evaluation was obtained from North West - Greater Manchester Central Research Ethics Committee as part of the ORBIT trial (REC: 18/NW/0079). All child and parent participants provided written informed consent and all interview participants provided oral consent for audio-recording.

Results

Characteristics of participants

A total of 112 CYP (mean age 12.2 years; range 9—17 years; males $n = 90$ [80%]) were randomised to the active intervention arm of the ORBIT trial and were included in the subsequent contextual, mediator and moderator analyses.

Clinically, the sample was moderately severe with a mean YGTSS-TTSS of 28.4 (SD = 7.7) out of a maximum of 50, with a range of 12—50. Fourteen (13%) participants were on medication for their tics.

Impact

Primary outcome

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean YGTSS-TTSS statistically significantly differed between baseline and primary end-point (F(1, 100) = 39.71, $p < 0.001$). There was a reduction in YGTSS-TTSS from baseline (M = 27.92, SD = 7.17) to primary end-point (M = 23.87, SD = 8.18) in the group which had received the intervention and this was statistically significant ($p < 0.001$). Cohen's d for the pre-post change in TTSS was 0.5 indicating a moderate effect.

Secondary outcome

Of 101 participants in the active intervention group, 36 (36%) were classified as 'responders' with their condition rated as being 'very much' or 'much improved' on the CGI-I. Thirty-seven (37%) were rated as 'minimally improved', 18 (18%) were rated as having no change in their condition, and 10 (9%) were rated as being minimally worse. No participants were rated as being much or very much worse in their condition since the initiation of treatment.

Correlations

Spearman's rank correlations were used to analyse associations between all contextual, mediator and moderator variables and the primary (YGTSS-TTSS change) and secondary (CGI-I) outcomes. Only YGTSS-TTSS at baseline ($\rho = -.26$, $p < .001$) was statistically significantly correlated with YGTSS-TTSS change so that higher scores at baseline were associated with a greater decrease in tic severity at the primary end-point. Child engagement factor score ($\rho = -23$, $p = .02$) and parental chapter completion ($\rho = -.25$, $p = .01$) were statistically significantly negatively correlated with CGI-I, suggesting that CYP with high levels of engagement with the intervention and CYP with parents who completed more chapters showed better overall clinical improvement at primary end-point.

Table 1 shows intercorrelations between YGTSS-TTSS change score, CGI-I, and contextual, mediator and moderator variables.

Contextual factors influencing impact

Following on from the correlational analysis, we explored whether parental engagement was an independent contextual predictor of YGTSS-TTSS change and overall clinical improvement (CGI-I). Multiple linear regressions were conducted with parental chapter completion, IMD, and maternal level of education as the independent variables. There was no evidence of multicollinearity, with all tolerances above 50%, and all variance inflation factors below 2. The results of the simultaneous regression indicated that collectively the independent variables did not predict YGTSS-TTSS change. However, the independent variables did explain a statistically significant amount of variance on CGI-I, F(3,97) = 3.14, $p = .029$, $R^2 = .09$. Parental chapter completion ($\beta = -.10$, t(100) = −2.41, $p = .018$) was the only significant independent predictor in the model.

Mediators

Simple mediation analyses found that the relationship between child's level of engagement (child engagement factor score) and either tic severity change (YGTSS-TTSS change) or CGI-I was not mediated by: (i) depression change (MFQ change); (ii) anxiety change (SCAS change); (iii) treatment satisfaction; (iv) treatment credibility.

Moderators

A moderator analysis was conducted to assess whether medication use, comorbidity, parental chapter completion, YGTSS-TTSS at baseline, age, deprivation (IMD), or mother's level of education moderated the relationship between child's level of engagement (child engagement factor score) and either of the outcome variables: YGTSS-TTSS change or CGI-I. No variables were found to moderate the relationship between child engagement factor score and outcome on either YGTSS-TTSS change or CGI-I.

Framework categories

From the analysis of the qualitative data, three categories were generated relating to participants perceptions of impact of the ORBIT intervention: 'Mechanisms of impact', 'Intervention outcomes', and 'ORBIT program content' (see Appendix for full analytic framework categories and themes).

Mechanisms of impact

Within this category, CYP highlighted the need to practise and how the interactive aspects of the intervention had helped with their tics (see Appendix for quotes from semi-structured interviews). Others mentioned that the extent to which they were able to visualise how the treatment and ''tic cycle'' worked had helped them. This visualisation also enabled child participants to see how, and which tics were increasing or decreasing in severity or frequency. Other participants felt that the use of the reward system motivated them to complete the practices within ERP whilst parents explained how during the middle of treatment their child began to disengage with the intervention and thus introduced the reward system which reignited their motivation levels.

Conversely, some participants felt that the nature of online therapy had certain barriers which may have impeded its impact with some CYP saying they would have preferred face-to-face therapy.

Qualitative analysis further highlighted the importance of parental engagement for CYP completing the treatment. In particular, CYP appreciated being able to complete the therapeutic activities and chapters with their family members. Parents also seemed to appreciate this time spent working

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Table 1 Intercorrelations between primary and secondary outcomes and contextual, mediator and moderator variables.

Variable	2	3	4	5	6	7	8	9	10	11	12	13	14
1. YGTSS-TTSS change	.51**	−.05	.11	.07	−.05	−.08	.09	.05	.01	−.26**	.13	−.04	−.02
2. CGI-I	—	−.23*	.04	.02	−.12	−.06	.05	−.25	−.25*	.05	.03	.00	.13
3. Child engagement factor score		—	−.01	.08	.47**	.31**	.04	−.19*	.73**	.08	−.14	.18	−.01
4. MFQ at baseline			—	.63**	−.25*	.05	−.15	.02	−.12	.30**	.06	.03	.03
5. SCAS at baseline				—	.04	.11	−.07	.24*	−.07	.26**	.02	.06	−.04
6. Treatment satisfaction					—	.56**	.08	−.21	.23*	−.13	−.19	.08	−.21
7. Treatment credibility						—	.12	−.14	.24*	.01	−.34**	.24*	.05
8. Medication status							—	.03	.00	−.04	.02	.00	−.08
9. Comorbidity status								—	−.13	.10	−.14	.04	−.20*
10. Parent completed chapters									—	−.01	−.22*	.16	−.02
11. YGTSS-TTSS at baseline										—	−.02	−.16	−.06
12. Age											—	−.08	−.07
13. IMD												—	.21*
14. Mother level of education													—

YGTSS-TTSS: Yale Global Tic Severity Scale Total Tic Severity Score; CGI-I: Clinical Global Impressions-Improvement Scale; MFQ: Mood and Feelings Questionnaire; SCAS: Spence Child Anxiety Scale; IMD: Index of Multiple Deprivation.
** $p < .001$.
* $p < .05$.

together as a team, which they felt may have led to more positive outcomes. Some parents also appreciated having therapist support. They particularly seemed to appreciate having an expert on hand if they required their assistance on anything that they were unsure about. Finally, one of the clinicians suggested that parental support seems to be the key factor of this online intervention.

Intervention outcomes
From this category, various themes were gathered which outlined the impact that the intervention had on CYP and parents. Participants felt that the intervention had allowed the severity and frequency of their tics to dissipate coinciding with the main findings from the trial. Although some parents expected that the intervention would be more effective than it had been and were somewhat disappointed by the outcome. Finally, some parents noticed how there was an improvement in their child's related psychological symptoms which they attributed to the intervention.

Online treatment content
In terms of what is known as ''essential ingredients'', the qualitative data seemed to shed some light on what these may constitute. Most CYP found the 'tic stopwatch' (timing how long they can suppress their tics) and 'tic ladder' (hierarchy of tics) to be the most useful to them. Many participants were also attracted to the videos and animations, which some found to be engaging and an effective alternative to large quantities of text presenting key information. Finally, it seemed that some of the older participants found the content and presentation of materials in the intervention to be ''child-like'' and aimed more towards younger

children. One of the therapists agreed with this sentiment, however felt that due to the large age range involved in ORBIT, they had to cater to all participants.

Discussion

In this second phase of a mixed methods process evaluation, we examined the impact of the intervention in terms of reduction in tic severity and global clinical improvement. Within the active intervention group, tic severity was reduced by 4 points from baseline to 3-month follow-up with a Cohen's *d* effect size of 0.5 and 36% were rated as very much improved or much improved on the CGI-I. A further 37% showed some improvement. This process evaluation, which aimed to understand mechanisms of impact, found that only tic severity at recruitment was associated with reduction of tic severity post-intervention. Level of usage as captured by the child engagement factor score (Khan et al., 2021) was not associated with improvement in tic severity however higher levels of child engagement and higher parental chapter completion were associated with higher levels of overall clinical improvement. Only parental chapter completion was independently associated with CGI-I scores. No mediators or moderators were identified for either reduction in tic severity or clinical improvement. This may be due to the high level of overall uptake of the intervention and the relatively modest impact compared to face-to-face therapy (Hollis et al., 2016). Furthermore, the study lacked the power to identify small effect sizes within the mediation analysis. From the qualitative data, CYP further emphasised the important role their parents played in this online inter-

vention and that their support was crucial in helping them to engage which may have led to more positive outcomes.

Engagement and parental support

Though child engagement with the intervention led to better overall improvement at primary end-point only on one of our outcome measures, the CGI-I, the findings of this study are broadly consistent with the literature (Bennett & Glasgow, 2009). Additionally, the association between parental chapter completion and positive outcomes is also consistent with previous research (Brigden et al., 2020; Haine-Schlagel & Walsh, 2015; Vernon, Koegel, Dauterman, & Stolen, 2012). The findings from this study suggest that parental involvement worked through encouraging CYP's engagement which led to positive outcomes, as CYP who were interviewed in the qualitative component of the current study emphasised that parental support was key for their levels of engagement. As parents had their own chapters to work through, they appeared to gain more knowledge of their child's tics and were able to understand them better. Furthermore, both CYP and parents' accounts of their experiences frequently cited being able to work together as a team as one of the main drivers for how they conducted their time on ORBIT. It was clear from the interviews that ORBIT managed to facilitate a symbiotic relationship between child and parent, which may have led to its impact.

In terms of what is known as ''essential ingredients'', this study appeared to shed some light on what these may constitute. Specific features such as the video demonstrations of therapy, animations, the ability to visualise which tics were increasing or decreasing in severity and frequency on the 'tic ladder', and the 'tic stopwatch' were all highlighted in interviews as an important mechanism of impact. Indeed, these interactive components were identified as key features of the intervention that seemed to be used most. This is consistent with evidence that interactive elements, including attractive audio-visual material to be amongst the most highly used features of DHIs as they tend to keep users' interest (Brouwer et al., 2011; Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004). This would be especially important to younger children whose concentration levels would not be maintained with material that was simply presented in writing, for example. Whilst many of the younger children appreciated the graphics and animations, older children felt they were somewhat ''child-like''. However, there was no evidence from the quantitative data that child age influenced engagement (Khan et al., 2021). Nor did it moderate the relationship between engagement and efficacy. Future work could explore practical ways of tailoring interventions to meet the needs of different age groups. Furthermore, a potential avenue for a future expansion of ORBIT could be in the form of a mobile app. Although adherence to the intervention was very good, it is possible that an app version may further enhance adherence rates. Although ORBIT was designed as a web-based program, an app version may facilitate accessibility and correspond more to the technology that CYP use in their daily lives.

Additionally, it appeared that the reward system was a useful resource for successful completion of ERP practices. This was evidenced by some parents stating that their child's engagement began to wane in the early to middle stages of treatment, whereby they felt the information presented was becoming somewhat repetitive. These parents would then introduce the reward system to facilitate continued use. This seemed to be an effective strategy to engage their child and ensure that they would maintain their level of commitment with the practices involved in ERP.

Mediators and moderators

The absence of significant findings in the mediator and moderator analyses in this study suggests that treatment efficacy was not significantly affected by sociodemographic or clinical characteristics of participants. Furthermore, interviews with parents, children and therapists also failed to reveal any perceptions of clinical factors influencing outcomes. Therefore, the findings from this study suggest that ORBIT is appropriate for a wide demographic of CYP with tic disorders, regardless of parental education or deprivation, age, baseline tic severity, tic medication use, anxiety or depression levels, or comorbidities. The lack of statistically significant findings is encouraging for clinical practice, suggesting that healthcare specialists can confidently recommend this digital intervention to most families.

There may be some potential explanations as to why no significant mediators or moderators were found. As a process evaluation, this study only included participants in the active intervention arm. Thus, we explored factors moderating the relationship between level of engagement and outcomes rather than the relationship between group membership and outcome. This meant that the sample size was diminished, thus creating low statistical power. It is well established that large sample sizes and substantial power are necessary to be able to detect mediator and moderator effects (MacKinnon, Lockwood, Hoffman, West, & Sheets, 2002; MacKinnon, Fairchild, & Fritz, 2007).

Strengths and limitations

The present study marks a comprehensive assessment of the contextual factors, mediators and moderators influencing the impact of an online ERP intervention delivered to CYP with tic disorders and is the first study to do so. A particular strength is that this study used a mixed-methods approach to data analysis, which enabled it to capture a more holistic and richer depth of understanding of the mechanisms through which the intervention achieved its impact. Furthermore, the absence of statistically significant mediators and moderators is notable to the extent that it suggests that this evidence-based therapy can be delivered online to a diverse range of CYP with tic disorders. This is encouraging from a clinical perspective — especially in light of the Covid-19 pandemic — as this has hastened the move away from more traditional forms of therapy (i.e., face-to-face) to digitally based approaches.

Current findings should be interpreted in light of several limitations. First, as this was part of a process evaluation, we only analysed the data from the active intervention group. Second, the ORBIT trial was designed and powered to evaluate the main effects of treatment and mediators and moderators of impact were secondary. This, by definition,

renders the mediator and moderator analyses as exploratory. Finally, the study also presented a major data analytic challenge for these types of analyses, including a relatively small sample size and subsequent lack of power. As a result of these limitations, it was not possible to exclude Type II errors (i.e., false negative findings).

Conclusion

Overall, the intervention had a positive impact on participants as it reduced the severity of their tics and improved overall clinical condition. This study found that parental engagement was a significant contextual predictor of overall improvement of tics; however, there was no evidence of mediators or moderators of outcomes to an online ERP intervention delivered to CYP with tic disorders. The results of these analyses suggest that engaging parents is a key factor in successful outcomes and that whilst online therapy seems an effective alternative to face-to-face therapy for CYP with tic disorders, there is no particular subgroup that is more or less likely to find this treatment beneficial. This is a positive finding from a clinical perspective, as it suggests that ORBIT can be implemented within routine healthcare to a broad range of CYP with tic disorders. However, more research needs to be carried out in this area with larger sample sizes and with a primary focus on the potential mediators and moderators of impact in order to fully understand the mechanisms through which online therapy has its desired effect.

In summary, ORBIT may be an effective and acceptable means of delivering an evidence-based ERP treatment to CYP with tic disorders. It is likely to increase access to effective behavioural therapy regardless of potential socioeconomic and clinical barriers. This process evaluation has also confirmed the important role of parents in enhancing the impact of online therapy for children and young people.

Consent to participate

Informed consent was obtained from all individual participants included in the study.

Research involving human participants and/or animals

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval for the conduct of the study was gained from the North West - Greater Manchester Central Research Ethics Committee (REC: 18/NW/0079).

CRediT authorship contribution statement

Kareem Khan: Conceptualisation, Methodology, Formal analysis, Investigation, Writing - Original Draft, Writing - Review & Editing. Chris Hollis: Writing - Review & Editing, Funding acquisition. Charlotte L Hall: Writing - Review & Editing,

Supervision, Project administration. E Bethan Davies: Writing - Review & Editing, Supervision. Elizabeth Murray: Writing - Review & Editing. Per Andrén: Writing - Review & Editing. David Mataix-Cols: Writing - Review & Editing. Tara Murphy: Writing - Review & Editing. Cris Glazebrook: Conceptualisation, Methodology, Writing - Review & Editing, Supervision.

Availability of data and materials

Part of the data generated or analysed during this study is included in this article and its supplementary information files or is available from the corresponding author on reasonable request. The full datasets generated or analysed during the current study are also available from the corresponding author on reasonable request.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.jbct.2022.02.005.

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