**Method of Levels therapy for first-episode psychosis: The feasibility randomised controlled Next Level trial**

Short title: Method of Levels for first-episode psychosis

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**Keywords**

Method of Levels; first-episode psychosis; psychotherapy; early intervention; randomised controlled trial; feasibility

**Abstract**

Objective: We aimed to determine the feasibility and acceptability of Method of Levels (MOL) for people experiencing first-episode psychosis to inform decision making about the therapy’s suitability for further testing in a larger clinical trial.

Method: A parallel group randomised controlled trial design was used. Participants (*N* = 36) were allocated to receive either treatment as usual (TAU) or TAU plus MOL. Recruitment and retention in the trial and the acceptability of the MOL intervention were the primary outcomes.

Results: The recruitment target was met within the planned timeframe. Retention in the trial at final follow up was 97%, substantially higher than the 80% threshold pre-specified as a successful feasibility outcome. Participant feedback provided initial evidence of the acceptability of the study design and intervention for this population.

Conclusion: Results support progressing to a larger trial of MOL for first-episode psychosis. Recommendations for the design of future trials are provided.

Trial registration: ISRCTN13359355

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**Introduction**

*Background*

Early intervention in psychosis services have demonstrated improved outcomes compared to routine care for service users experiencing first-episode psychosis (FEP) (Bertelsen et al., 2008; Craig et al., 2004). Delivery of evidence-based psychological interventions is an important function of early intervention teams (Bird et al., 2010). Clinical guidelines in the United Kingdom recommend that everyone using early intervention services should be offered cognitive behavioural therapy for psychosis (CBTp) (National Institute for Health and Care Excellence [NICE], 2014). There is relatively good evidence to suggest that CBTp helps to reduce psychotic symptoms, with most meta-analyses reporting effect sizes in the small to moderate range (Jauhar et al., 2014; Turner, van der Gaag, Karyotaki, & Cuijpers, 2014; Wykes, Steel, Everitt, & Tarrier, 2008). However, there have been significant difficulties with the implementation of CBTp into routine clinical practice (Ince, Haddock, & Tai, 2015), and access to CBTp amongst users of early intervention services remains low (Royal College of Psychiatrists, Healthcare Quality Improvement Partnership, & NHS England, 2016). Additionally, given the high levels of comorbidity (Achim et al., 2011; Addington, Addington, & Patten, 1998) and diverse sources of distress (Griffiths, Mansell, Edge, & Tai, 2019) amongst people experiencing psychosis, questions have been raised about the extent to which disorder-specific approaches such as CBTp can fully meet the complex needs of this population (Griffiths et al., 2018). Transdiagnostic interventions that directly target core cognitive and behavioural processes which are proposed to maintain distress might have advantages over disorder-specific approaches (Mansell, Harvey, Watkins, & Shafran, 2008), particularly for people experiencing psychosis (Tai, 2009, 2016).

*Method of Levels*

The Method of Levels (MOL) (Carey, 2006) is a transdiagnostic cognitive therapy based on the principles of perceptual control theory (Powers, 2005). The theory proposes that the phenomenon of control is fundamental to the survival of all living things. This is achieved through a hierarchical and parallel arrangement of negative feedback loops that control perceptual variables according to ‘reference values’ (synonymous with ‘goals’ or ‘just-right states’) that specify the desired state of the variables. The function of human behaviour, from this perspective, is to minimise any disparity between perceptual variables and reference values. People are able to control a wide variety of variables, from relatively simple perceptions lower in the hierarchy (e.g. body posture or temperature), to those higher in the hierarchy that are more complex and abstract in nature (e.g. sense of self and identity). Control is disrupted in situations where people simultaneously hold conflicting reference values for the state of the same variable. Perceptual control theory proposes that we are able to resolve conflict through an innate trial-and-error system called ‘reorganisation’. Sustaining awareness on the source of the conflict is believed to facilitate the reorganisation of goals, enabling people to regain control.

MOL has been fully described in several treatment manuals (Carey, Mansell, & Tai, 2015; Carey, 2006; Mansell, Carey, & Tai, 2013). It aims to directly target goal conflict and facilitate the reorganisation process. To achieve this, therapists delivering MOL have two goals. The first is to encourage the person to talk freely about whatever their current focus of attention is. The second goal is to pay attention to ‘disruptions’ (potential signs of fleeting shifts in awareness) and ask the person to discuss these when they occur. Disruptions often indicate that the person’s awareness has momentarily shifted to potentially relevant background thoughts. Asking about disruptions provides opportunities to ‘go up levels’ of the perceptual hierarchy, eventually shifting awareness onto the source of the conflict. Sustaining awareness on the conflict and then its source facilitates the reorganisation process, leading to a reduction in distress as a consequence.

Because reorganisation is assumed to be non-linear and idiosyncratic, the exact number and frequency of MOL sessions required will differ between individuals. For this reason, MOL uses a system of service user-led appointment scheduling. There is no minimum or maximum number of sessions that people are expected to attend. Instead, service users are made aware of when MOL sessions are available and have control over booking appointments as they require them. Existing research suggests that clients appreciate having greater control over appointment scheduling, and this system has the potential to use resources more efficiently than conventional approaches to appointment scheduling (Carey & Mullan, 2007; Carey, Tai, & Stiles, 2013).

Several case studies and pragmatic uncontrolled trials have found that MOL is a helpful means of reducing distress for people experiencing a diverse range of problems in a variety of practice settings (Carey & Mullan, 2008; Carey, Carey, Mullan, Spratt, & Spratt, 2009). Carey et al., (2013) conducted a practice-based study of MOL in a rural Australian secondary care mental health setting and reported an effect size of 1.45 on the Outcome Rating Scale (Miller, Duncan, Brown, Sparks, & Claud, 2003). The mean number of sessions attended was 3.6 (median 3, range 2-11). The effectiveness of MOL, therefore, was comparable to other psychological therapies evaluated in equivalent practice-based studies, but it was significantly more efficient. Initial qualitative research also suggests that service users find attending MOL sessions to be a useful experience (Carey et al., 2009). See Alsawy, Mansell, Carey, McEvoy, & Tai (2014) for a detailed review of current evidence supporting the use of MOL.

*Study rationale*

MOL has several potential advantages over existing treatments for FEP. Firstly, MOL focuses on reducing underlying distress rather than on the treatment of specific symptoms, making it applicable to situations where service users are reporting multiple problems. Secondly, the principles underpinning the delivery of MOL remain the same, irrespective of the exact problems upon which a service user chooses to work. This has the potential to make the training and supervision of professionals delivering psychological interventions more efficient. Thirdly, the focus of MOL sessions is determined by the service user, tailoring therapy to the specific needs of the individual. Fourthly, service user-led scheduling gives people greater control over the psychological interventions they receive. Fifthly, the practice of MOL is guided by clearly defined principles derived from perceptual control theory, a robust theory of human behaviour (Marken & Mansell, 2013).

*Aims of the study*

The current study, called ‘Next Level’, aimed to establish the feasibility and acceptability of MOL for people experiencing first-episode psychosis and determine its suitability for further testing in a clinical trial. As part of the Next Level study, a nested qualitative study exploring participants’ experiences of receiving MOL was conducted (Griffiths, Mansell, Edge, Carey, et al., 2019). No previous studies had investigated the use of MOL for FEP, so a feasibility trial was required before a larger effectiveness trial could be justified. The specific research questions that this feasibility trial aimed to answer were:

1. Is it feasible to recruit and retain people experiencing FEP in a randomised controlled trial of MOL?
2. Is it feasible to deliver MOL to people experiencing FEP?
3. Is MOL an acceptable psychological intervention for people experiencing FEP?
4. Are adaptations necessary to overcome problems or barriers to the implementation of MOL in early intervention services?

**Methods**

*Trial design*

The study used a parallel group design with random allocation to two conditions: (1) treatment as usual (TAU) or (2) TAU plus MOL. Participants were allocated to one of the two groups by the study’s chief investigator (RG) in random permuted blocks using an online randomisation service (Sealed Envelope Ltd. 2017. Simple randomisation service. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/ [Accessed 30 Jul 2018]). Group allocation was in a ratio of 1:1 and future allocations were concealed until participants were randomised. The study sample was not stratified. Enrolment was completed by the study’s chief investigator. To minimise bias, participants were randomised in the order of completing baseline assessments. Participants, the clinicians involved in their routine care, the research team, and the trial therapist were not blinded to group allocation. In a future effectiveness trial, the intention would be for outcome assessors to remain blind to group allocation. A nested qualitative study was also undertaken to investigate participants’ experiences of trial participation, the MOL intervention, and the service user-led appointment booking system. The results of this qualitative study have been reported separately (Griffiths, Mansell, Edge, Carey, et al., 2019). The trial was prospectively registered with the ISRCTN registry ([ISRCTN13359355](http://www.isrctn.com.ISRCTN13359355)).

*Participants*

Participants were recruited from Greater Manchester Mental Health NHS Foundation Trust early intervention in psychosis services. Leaflets, posters, and training sessions were used to raise awareness with clinicians working in these services. Clinicians were invited to discuss the study with service users on their caseloads. Service users who expressed an interest in finding out more about the study were contacted by the research team by telephone. Providing verbal consent was given at this point, potential participants were invited to a face-to-face meeting where they were given more information about the study and completed a brief eligibility screen (consisting of the study’s inclusion and exclusion criteria). Eligible service users were then asked to provide written consent to participate in the study. Participants received a payment for completing follow up assessments at 10 and 14 months.

*Inclusion and exclusion criteria*

People meeting the following criteria were eligible to participate in the study: aged 16-65 years; current user of Greater Manchester Mental Health NHS Foundation Trust early intervention services; sufficient English language abilities (verbal and written) to complete written material (for example, outcome measures) and participate in psychological therapy; and be willing and able to provide informed consent. People were not eligible to participate in the study if they did not meet all of the inclusion criteria or if they were serving a custodial prison sentence.

*Interventions*

*Treatment as usual group.* Participants in the TAU group continued to receive ongoing support from their usual early intervention team. This consisted of regular meetings with a care coordinator, and less frequent reviews by the psychiatrist involved in their care. Participants had ongoing access to the full range of psychosocial and pharmacological interventions usually offered by their early intervention service.

*Method of Levels group.* Participants in this group were able to choose the number and frequency of MOL sessions that they attended over a 10-month treatment window. No limits were placed on the minimum or maximum number of sessions participants could attend. MOL appointments were arranged using a dedicated booking website, by telephone, or by SMS text message, depending on participant preference. MOL sessions were delivered at two community resource centres, one based in each recruitment site. Sessions were routinely available on two days of the week during working hours. Participants were made aware that sessions could be offered on other days or in the evening if required. The availability of MOL sessions was kept under review to ensure sufficient appointment slots were available to meet participant demand. Participants in this group were also able to access any interventions that would usually be available to them from their early intervention service.

MOL sessions were delivered by the first author, a mental health nurse with several years’ experience of delivering psychological interventions within early intervention services who has completed postgraduate training in CBT for psychosis. Clinical supervision was provided by ST, WM, and TC, who are experienced MOL trainers and practitioners.

*Trial oversight*

A trial steering committee (TSC) was established to provide trial oversight. The TSC comprised clinical, academic, and service user representatives. As a small feasibility trial, a separate data monitoring and ethics committee (DMEC) was not deemed necessary. Instead, the TSC took on some of the functions normally performed by a DMEC.

*Ethical approval*

All approvals were in place prior to commencing recruitment. Ethical approval was received from the North West – Greater Manchester Central Research Ethics Committee (REC reference: 16/NW/0592; IRAS project ID: 204043). The research was sponsored by The University of Manchester.

*Safety monitoring and reporting*

Potential adverse events (AE) and serious adverse events (SAE) were reported to the primary investigator and chair of the TSC, who determined whether the event was likely to be related to participation in the trial. To increase the chances of detecting potential SAEs and AEs, the chief investigator reviewed the clinical records of participants who experienced an increase of five or more in overall risk score as measured on the CORE-OM (Evans et al., 2002). Also, at the end of the trial, all participants were invited to complete a measure designed to detect potential adverse events in psychotherapy studies (Hutton, Byrne, & Morrison, 2017).

*Sample size*

Since the aim of the study was not to compare the effects of treatment between groups, a formal power calculation was not performed. A sample size of 15 participants per group was considered adequate for addressing the study’s feasibility questions. To allow for potential attrition, a recruitment target of 36 participants was set.

*Primary outcomes*

Primary outcomes were consistent with CONSORT guidelines for feasibility and pilot trials (Eldridge et al., 2016). These were successful recruitment to the trial, retention and attrition at final follow-up, and acceptability of the MOL intervention. Over 80% was deemed to be a successful retention rate, over 70% was a borderline outcome, and below 60% was considered unacceptably low. These thresholds are consistent with a recent meta-analysis of retention rates in studies investigating complex interventions for schizophrenia (Szymczynska, Walsh, Greenberg, & Priebe, 2017). We also report on attendance, cancellation, and non-attendance rates for MOL sessions. Sessions not attended as planned or not cancelled prior to the scheduled appointment time were classed as a non-attendance.

Unlike trials of psychological therapy where participants are expected to attend a predetermined number of sessions, this study’s use of service user-led scheduling meant it was not possible to measure “treatment drop-out” prior to the closure of the treatment window. To better understand this, at 14-month follow up, participants in the MOL group were asked to complete a brief questionnaire that asked about their reasons for ending therapy. Participants could choose one of the following options: (i) ‘I stopped attending because I got what I needed from the sessions’; (ii) ‘I stopped attending because I did not get what I needed from the sessions’; (iii) ‘I ran out of time’; or (iv) ‘I stopped attending for other reasons’. An accompanying free text box gave participants an opportunity to expand on their answer. These data were used in conjunction with the findings of the nested qualitative study to evaluate the acceptability of MOL for this population.

At final follow up, participants in both groups were invited to provide written comments on their experience of trial participation generally.

*Secondary outcome measures*

*Psychological Outcome Profiles (PSYCHLOPS)* (Ashworth et al., 2004)*.* This is the proposed primary clinical outcome measure for future studies. It is a brief participant-generated outcome measure that assesses the domains of wellbeing, functioning, and distress. Cronbach’s alpha was found to be 0.81 in a clinical sample, demonstrating satisfactory internal reliability (Czachowski, Seed, Schofield, & Ashworth, 2011).

*CORE-OM* (Evans et al., 2002)*.* This 34-item self-report measure is designed to measure subjective wellbeing, symptoms, functioning, and risk. It shows good sensitivity to change in a number of practice settings and has demonstrated satisfactory internal reliability in a clinical sample, with a Cronbach’s alpha of 0.94 (Evans et al., 2002).

*Reorganisation of Conflict Scale (ROC)* (Higginson & Mansell, 2008)*.* An 11-item sub-scale of the ROC was used to measure goal conflict reorganisation, the proposed mechanism of change in MOL. The sub-scale has shown satisfactory internal reliability, with a Cronbach’s alpha of 0.83 (Bird, 2013)

*Questionnaire about the Process of Recovery (QPR)* (Neil et al., 2009)*.* The QPR is designed to measure personal recovery from psychosis. It comprises two sub-scales: interpersonal functioning and intrapersonal functioning. Cronbach’s alpha was 0.77 for the interpersonal scale and 0.94 for the intrapersonal scale, indicating good internal consistency (Neil et al., 2009).

*Outcome Rating Scale (ORS)* (Miller et al., 2003)*.* Individual, social, relational, and overall functioning were measured using this visual analogue scale, which is scored from 0 to 40. Scores below 25 indicate clinically severe levels of psychological distress. Cronbach’s alpha was found to be 0.93, indicating good internal consistency (Miller et al., 2003).

*Session Rating Scale (SRS)* (Duncan et al., 2003)*.* Participant’s perception of the therapeutic alliance in MOL sessions was measured using this visual analogue scale, which is scored from 0-40. Scores of 36 or below indicate potential concerns about the therapeutic alliance or the suitability of the therapist’s approach. Cronbach’s alpha was found to be 0.88, indicating satisfactory internal consistency (Duncan et al., 2003).

A summary of the assessment schedule is presented in Appendix I.

*Statistical analysis*

The statistical analysis was conducted in accordance with the principles of intention-to-treat analysis, so all participants, including those who attended no MOL sessions, were included in the analysis. Descriptive statistics were used to summarise the feasibility outcomes. The CONSORT guidance for feasibility trials (Eldridge et al., 2016) states that effectiveness testing is not recommended. Since the study was not designed to detect between-group differences, therefore, results primarily focus on tabulated summaries of means and standard deviations for both groups, on all measures, at all time points. ANCOVA were conducted using SPSS (Version 22.0, 2013) to provide an initial estimate of the effect of group allocation on PSYCHLOPS scores at 10 and 14 months, adjusting for PSYCHLOPS scores at baseline. Because effect size calculations with fewer than 35 participants in each arm are likely to be unreliable (Teare et al., 2014), we report estimated effect sizes and their associated 95% confidence intervals, rather than statistical significance (*P*-values). Prior to the main analysis, data were checked to ensure they met assumptions of normality, homogeneity of variance, and that the covariate was independent of treatment effects. Analysis was performed on all available data, and missing outcome data were assumed to be missing at random.

**Results**

Next Level recruited to target at an average rate of 4.5 participants a month between September 2016 and April 2017. Data collection was completed in June 2018. Participant demographics and clinical characteristics are presented in Table 1. It is notable that the average duration of untreated psychosis (DUP) was longer in the MOL group. Mean DUP for the TAU group in months was 14.6 (SD 21.8; median 6; 25th percentile 3; 75th percentile 12). For the MOL group, mean DUP in months was 46.1 (SD 60.8; median 25.5; 25th percentile 9; 75th percentile 58.5). A CONSORT diagram showing the flow of participants through the trial is available in Figure 1. One participant was lost to follow up at 14 months, giving an overall trial retention rate of 97%. This is above the 80% rate deemed to be a successful feasibility outcome. The participant lost to follow up also disengaged from all mental health services during the same period, suggesting that withdrawal was not specific to trial participation.

**[Insert Table 1 around here]**

**[Insert Figure 1 around here]**

The total number of MOL sessions booked by all participants was 92. Of these, 57 (62%) were attended as planned, 27 (29.3%) were cancelled by participants, and 8 (8.7%) were not attended. Two participants accounted for 59.3% of the total number of cancelled sessions. The mean number of sessions attended by each participant was three (SD 3.3; median 2; range 0-10). The mean number of cancelled sessions was 1.4 (SD 2.6; median 0; range 0-10). The mean number of sessions not attended by participants was 0.4 (SD 0.6; median 0; range 0-2). Among the 14 participants who attended at least one MOL session, the mean number of sessions was 4.1 (SD 3.2; median 3.5; range 1-10), and the mean length of time from the start of the treatment window to attendance of first MOL session was 6 weeks (SD 6; median 3.5; range 1-23). The mean length of time from final MOL session attendance to end of treatment window was 22 weeks (SD 14.9; median 20.5; range 1-42). Four participants continued to book MOL sessions in the last month of the treatment window. The mean length of individual therapy sessions in minutes was 48 (SD 19.3; range 7-107).

Participants gave a variety of responses when asked about their reasons for stopping or not attending therapy sessions. A proportion of participants reported that they stopped attending sessions because they had already got what they needed from therapy (*n = 3*; 18.8%), others said that they ran out of time (*n* = 6; 37.5%), and some endorsed an ‘other’ option (*n* = 7; 43.8%), such as available therapy appointments coinciding with work and educational commitments. No participants reported that they stopped attending because they were not getting what they needed from therapy sessions.

Participants in both groups gave broadly positive accounts of their experience of trial participation. In the MOL group, participants particularly valued the flexibility of the appointment scheduling system and having the opportunity to speak openly about problems. One participant in the MOL group reported that they found it difficult to talk about their life, and another said they found it helpful to talk in MOL sessions but that they ran out of time and would have appreciated further therapy sessions. Participants in the TAU group also reported that they valued the opportunity to talk about problems to the researcher. One participant in the TAU group reported that completing questionnaires was difficult, and another described feeling disappointed that they were not allocated to the MOL group.

Summary statistics for both groups on all measures at all time points are presented in Table 2. Because assumptions of normality and homogeneity of variance were not met for all data, bootstrapped one-way ANCOVA were conducted to compare the effects of group allocation on PSYCHLOPS scores at 10 months and 14 months, controlling for the effects of PSYCHLOPS scores at baseline. Effects were as follows at 10 months, effect = -0.59 (standard error=2.13; 95% confidence interval -5.12 to 3.03), and 14 months, effect = -0.11 (SE=1.90; 95% CI -3.86 to 3.74).

**[Insert Table 2 around here]**

Over the course of the trial, four incidents involving participants were investigated in detail to check whether they met the criteria for classification as serious adverse events (SAE). After being reviewed by the research team and members of the TSC, none of the incidents were judged to be related to trial participation. No significant problems were detected using the Adverse Events Measure (Hutton et al., 2017). Participant responses to the Adverse Events Measure and their general comments on trial participation are available from the first author on request.

The mean score on the Session Rating Scale (Duncan et al., 2003) was 37.03 (SD 4.09, range 24.5-40), which is above the threshold of 36 indicating that there were not apparent difficulties or problems with the therapist’s approach or the therapeutic relationship.

Three participants in the TAU group reported receiving one or more sessions of CBTp as part of their routine care, and one had received sessions of supportive counselling accessed through their university. Although they were not discouraged by the research team from accessing other forms of support, none of the participants in the MOL group reported receiving any psychological interventions outside of the trial.

**Discussion**

This is the first randomised controlled trial of MOL for people experiencing FEP. Recruitment to the trial progressed well, and the recruitment target was met within the anticipated time frame. A retention rate of 97% at final follow up was above the 80% benchmark deemed to be a successful outcome.

Feedback from participants who received MOL suggests that they generally found it to be a helpful experience. None of the participants in the MOL group reported that they stopped attending therapy because it was not meeting their needs, which suggests the intervention is acceptable to people experiencing FEP. This is supported by data collected using the Session Rating Scale (Duncan et al., 2003) and the findings of the nested qualitative study (Griffiths, Mansell, Edge, Carey, et al., 2019). Having control over therapy, being able to speak openly about problems, and having the opportunity to develop new perspectives were particularly valued by participants receiving MOL. This is consistent with research that indicates feeling in control of therapy is a good predictor of service user-perceived helpfulness (Cocklin et al., 2017). It also supports the findings of existing qualitative research that suggests having the opportunity to talk to another person about distressing problems is a helpful aspect of psychological therapy (Carey et al., 2007).

Feedback on the experience of trial participation from participants in both the MOL and TAU groups seemed to indicate that it was a predominantly positive experience. Having the opportunity to discuss problems was valued by many participants in both groups. Participants reported appreciating receiving payment for completing follow up assessments. Having a sense of helping others in a similar situation was also seen as a positive aspect of trial participation. One participant in the TAU group reported that completing questionnaires was somewhat problematic. This is consistent with research that suggests participants in clinical trials can find it hard to convey complex experiences through scoring systems used in outcome measures (Holmberg, Karner, Rappenecker, & Witt, 2014). Another TAU participant described feeling disappointed that they were not allocated to receive MOL.

The mean number of MOL sessions attended over the course of the treatment window was three (range 0-10). This is substantially fewer than the 16 sessions of CBTp currently recommended as a minimum course of treatment in the United Kingdom (National Institute for Health and Care Excellence (NICE), 2014). This finding is consistent with other research indicating that service users who have control over accessing psychological interventions tend to book a relatively small number of sessions compared to the amount generally recommended by practice guidelines (Carey et al., 2013). The proportion of MOL sessions that were cancelled was 29.3%, although the majority of these were accounted for by two participants. Cancellations did not have a noticeable impact on the overall efficiency of the appointment booking system because these appointment times were made available to other participants. The number of appointments not attended or cancelled was 8.7%. Because attendance figures are rarely reported in trials of psychological therapy for psychosis, it is difficult to judge how these rates compare to similar studies. Rates of non-attendance for the increasing access to psychological therapies (IAPT) programme in the United Kingdom are estimated to be between 45% and 48% (Marshall et al., 2016). Although IAPT is designed for people with common mental health problems, rather than for people experiencing FEP, these figures suggest that service user-led scheduling might have advantages in terms of efficiency over other approaches to appointment scheduling.

Some participants reported that they stopped attending MOL sessions because they had got what they needed from the sessions. However, a larger number said that they ran out of time and would have attended more sessions if the treatment window had been longer. The pressure of other commitments (e.g. work, healthcare appointments) was frequently cited by participants as a reason for not attending as many sessions as they would have liked. Also, four participants continued to book sessions in the last month of the treatment window. A larger trial should consider offering a longer treatment window and increase the accessibility of MOL sessions to ensure they are available at times and locations that are convenient for all participants.

No potential SAEs were deemed attributable to trial participation, providing evidence that both the research design and MOL intervention are safe for this population.

Data collected from standardised outcome measures did not appear to favour the MOL intervention over TAU. As a small feasibility trial, however, the study was not designed to detect such between-group differences, and the wide confidence intervals around the estimates of effect size should be noted.

Very few participants in the TAU group, and no participants in the MOL group, accessed any other psychological interventions over the course of the trial. This finding is consistent with research suggesting that relatively few users of early intervention services currently receive psychological interventions in line with recommended treatment guidelines (Royal College of Psychiatrists et al., 2016).

Limitations

The number of roles the first author performed within the trial (recruitment, enrolment, conducting baseline assessments, delivery of therapy, and collection of follow up data) potentially increased the risk of bias. Additionally, the research team were not blind to group allocation, which also increases the risk of potential bias. Although treatment by an early intervention service could be considered an active control, participants in TAU were not systematically offered any psychological interventions. Differential access to psychological interventions between the two groups could, therefore, be considered a limitation of the study. Given that longer DUP is associated with poorer long term outcomes (Marshall et al., 2005), the disparity in DUP between groups could be a confounding factor and future trials should consider stratifying on this variable.

Because participants in the MOL group often had relatively long periods between their final therapy session and follow up assessments, a larger trial should consider whether the assessment schedule should be adjusted to increase the likelihood of detecting potential treatment effects.

Conclusions

This study demonstrates that it is feasible to recruit and retain participants experiencing FEP in a randomised controlled trial of MOL. It also provides prima facie evidence of MOL’s acceptability for people with FEP. These findings support the view that progressing to a larger trial of MOL for FEP is justified.

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