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ORIGINAL ARTICLE

Evaluation of a positive psychotherapy group intervention for people with psychosis: pilot randomised controlled trial

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Aims. Third-wave psychological interventions have gained relevance in mental health service provision but their application to people with psychosis is in its infancy and interventions targeting wellbeing in psychosis are scarce. This study tested the feasibility and preliminary effectiveness of positive psychotherapy adapted for people with psychosis (WELLFOCUS PPT) to improve wellbeing.

Methods. WELLFOCUS PPT was tested as an 11-week group intervention in a convenience sample of people with psychosis in a single centre randomised controlled trial (ISRCTN04199273) involving 94 people with psychosis. Patients were individually randomised in blocks to receive either WELLFOCUS PPT in addition to treatment as usual (TAU), or TAU only. Assessments took place before randomisation and after the therapy. The primary outcome was wellbeing (Warwick-Edinburgh Mental Well-Being Scale, WEMWBS). Secondary outcomes included symptoms (Brief Psychiatric Rating Scale), depression (Short Depression-Happiness Scale), self-esteem, empowerment, hope, sense of coherence, savouring beliefs and functioning, as well as two alternative measures of wellbeing (the Positive Psychotherapy Inventory and Quality of Life). Intention-to-treat analysis was performed. This involved calculating crude changes and paired-sample *t*-tests for all variables, as well as ANCOVA and Complier Average Causal Effect (CACE) Analysis to estimate the main effect of group on all outcomes.

Results. The intervention and trial procedures proved feasible and well accepted. Crude changes between baseline and follow-up showed a significant improvement in the intervention group for wellbeing according to all three concepts assessed (i.e., WEMWBS, Positive Psychotherapy Inventory and Quality of Life), as well as for symptoms, depression, hope, self-esteem and sense of coherence. No significant changes were observed in the control group. ANCOVA showed no main effect on wellbeing according to the primary outcome scale (WEMWBS) but significant effects on symptoms ($p = 0.006$, ES = 0.42), depression ($p = 0.03$, ES = 0.38) and wellbeing according to the Positive Psychotherapy Inventory ($p = 0.02$, ES = 0.30). Secondary analysis adapting for therapy group further improved the results for symptom reduction ($p = 0.004$, ES = 0.43) and depression ($p = 0.03$, ES = 0.41) but did not lead to any more outcomes falling below the $p = 0.05$ significance level. CACE analysis showed a non-significant positive association between the intervention and WEMWBS scores at follow-up ($b = 0.21$, $z = 0.9$, $p = 0.4$).

Conclusions. This study provides initial evidence on the feasibility of WELLFOCUS PPT in people with psychosis, positively affecting symptoms and depression. However, more work is needed to optimise its effectiveness. Future research might evaluate positive psychotherapy as a treatment for comorbid depression in psychosis, and consider alternative measurements of wellbeing.

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Key words: Positive psychology, psychosis, psychotherapy, randomised controlled trial, schizophrenia, wellbeing.

Background

Although there is evidence that people who suffer from psychosis can have a favourable prognosis (Zipursky *et al*. 2013), up to one-third of patients with schizophrenia suffer persistent psychotic symptoms despite adequate treatment (Miyamoto *et al*. 2014). Consequently, new therapeutic approaches are being developed and tested, both biological and psychological. In terms of psychological treatment strategies, cognitive behavioural therapy (CBT) has the most advanced evidence base and is recommended for people at all stages of a psychotic illness (NICE,

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2009). Recent meta-analytic evidence suggests a beneficial effect of CBT for a range of subgroups of people with schizophrenia (Burns *et al*. 2014) partly depending on the methods used in the respective trials (Jauhar *et al*. 2014).

Other new psychological interventions that have received increasing attention in recent years include so called 'third wave' CBT (Kahl *et al*. 2012) or more humanistic and psychodynamically oriented approaches which gained additional prominence with the establishment of Positive Psychology in the late 1990s (Sin & Lyubomirsky, 2009). These therapeutic approaches often do not directly target symptom reduction or functioning, but instead focus on subjective psychological variables such as wellbeing, life satisfaction or meaning. Meta-analytic evidence supports the effectiveness of positively oriented approaches for these variables, but also for the secondary improvement of symptoms (Sin & Lyubomirsky, 2009; Bolier *et al*. 2013). While some positive interventions, e.g., mindfulness therapy (Chadwick, 2014), have already been tested with people with psychosis, overall, research on the application of positive interventions in this client group is still in its infancy.

The academic discipline of Positive Psychology focuses on improving wellbeing by addressing positive aspects of human experience, strengths and positive resources (Seligman *et al*. 2005). Positive psychotherapy (PPT) constitutes the most comprehensive therapeutic application of positive psychology principles (Rashid & Seligman, 2013). It was developed for people with depressive symptoms and initial evaluation showed promising results for improving wellbeing and ameliorating depression (Sin & Lyubomirsky, 2009; Bolier *et al*. 2013). So far, PPT has been mainly applied to healthy people and those with depression, but research in mental health settings is increasing and can overall be regarded as preliminary but promising (Schrank *et al*. 2014). PPT principles appear to be applicable to people with psychosis (Meyer *et al*. 2012), but it has not been systematically adapted for this client group or tested using a randomised controlled design (Schrank *et al*. 2014).

We adapted PPT following the Medical Research Council (MRC) Guidelines for the development and evaluation of complex interventions (Craig *et al*. 2008). This involved a systematic literature review (Schrank *et al*. 2013*a*), qualitative study (Schrank *et al*. 2013*b*) and expert consultation (Riches *et al*. 2014). The new intervention, WELLFOCUS PPT, is intended to augment existing mental health practice to increase wellbeing. It is hypothesised to also positively affect other indicators of improved wellbeing, i.e., positive emotions, symptom relief, connectedness, hope, self-worth, empowerment and meaning in life. These variables were identified in preceding qualitative work with the client group with the specific aim to understand the concept of wellbeing and the processes involved in improving it (Schrank *et al*. 2013*b*) The aim of this pilot randomised controlled trial was to inform the design of a future definitive RCT. The objectives were (1) to test relevant trial procedures, especially in relation to (i) referral and consent rates, (ii) allocation procedures, (iii) attendance and loss to follow-up, (iv) fidelity approaches and (v) outcome assessment; and (2) to establish preliminary evidence about the effectiveness of the intervention for improving wellbeing, to inform a future sample size calculation.

Methods

Design

This study was a pilot RCT according to MRC guidelines for the development and evaluation of complex interventions (Craig *et al*. 2008). Recommendations for pilot trials (Lancaster *et al*. 2004; Thabane *et al*. 2010), were followed, and a trial protocol was published (Schrank *et al*. 2013*c*). The study received ethical approval (12/LO/1960).

A target sample size of 30 complete data sets in each trial arm was chosen according to recommendations for pilot trials (Lancaster *et al*. 2004). Recruitment took an expected 25% drop-out into account. The obtained sample size allowed effectiveness at a medium effect size (Cohen's $d = 0.5$) to be detected with 90% power at a 5% significant level, taking into account 20% attrition.

Participants

Inclusion criteria were: aged 18–65 years; primary clinical diagnosis of psychosis defined as schizophrenia and other psychoses including schizoaffective and delusional disorder but not depressive psychosis or psychosis due to substance misuse; current use of adult mental health services; fluency in English; and ability to give informed consent and participate in group therapy in the opinion of the key clinician.

Intervention and control condition

Control group participants received treatment as usual (TAU), consistent with the Care Programme Approach (Department of Health, 1999), comprising systematic assessments of health and social needs, formation of a care plan, appointment of a key worker to monitor and co-ordinate care, and regular reviews to adapt the care plan. Care is provided by multidisciplinary mental health teams, and treatments may include medication, social or psychological interventions.

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There was no restriction on changes to concurrent routine drug, psychological or social therapies. No psychological intervention based on positive psychology principles was routinely provided in the NHS services from which participants were recruited.

Intervention group participants received TAU and 11 weekly 90-min sessions of WELLFOCUS PPT in a closed group format, delivered by a therapist and co-therapist. Six therapy groups ran between May and October 2013. The five involved therapists were routine NHS staff. Four of them were clinical psychologists with standard psychotherapy training, mainly CBT-focused, who were experienced in delivering both individual and group therapeutic interventions to people with psychosis. One was a trainee clinical psychologist under supervision. The three co-therapists were members of the research team, one psychiatrist with a clinical education in CBT and two post-graduate psychologists. All therapists and co-therapists were offered a 1.5 day intensive training course and monthly peer supervision which included the developers of the intervention and project staff who repeatedly provided the intervention as co-therapists. Training covered the differences between WELLFOCUS PPT and CBT.

WELLFOCUS PPT is described in detail elsewhere (Riches *et al*. 2014). In brief, it targets four areas of development: increasing positive experiences; amplifying strengths; fostering positive relationships; and creating a more meaningful self-narrative. These areas are addressed using ten exercises adapted from standard PPT: positive introductions, savouring, good things, identifying personal strengths, personal strength activity, strength activity with significant other, forgiveness, one door closes another door opens, gratitude and positive responding. Sessions begin and close with a music savouring exercise. In contrast to standard PPT, WELLFOCUS PPT has a reduced focus on literacy and didactics but instead includes more experiential and interactive components. All exercises and homework tasks are tailored to the individual to be specific, attainable and personally meaningful. Distinctive features are the importance of valuing small things and the participation of therapists in all exercises. Negative issues and experiences are dealt with by identifying and using positives, e.g., personal strengths, to develop coping strategies. Participants receive a phone call between sessions to support them with homework and reflect on what they have learnt.

Measures

The choice of outcome measures was informed by preceding conceptual research (Schrank *et al*. 2013*b*). The primary outcome measure was the 14-item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) which measures positive personal wellbeing framed as a multidimensional construct with mean scores between 1 and 5 (Tennant *et al*. 2007). The scale integrates several of the pre-existing concepts and measurement tools for wellbeing and has proven feasible, reliable and sensitive to change in people with various mental health problems, including some participants with psychosis (Margrove *et al*. 2012). Cronbach's α for the scale lies between 0.87 and 0.91 and the 1-week test–retest reliability at $r = 0.83$ (Tennant *et al*. 2007; Clarke *et al*. 2011).

Two alternative wellbeing measures were used: (i) the 25-item positive psychotherapy inventory (PPI) measures a PPT-specific concept of wellbeing with mean scores between 1 and 5 (Guney, 2011), and (ii) the 12-item Manchester Short Assessment (MANSA) measures quality of life framed as satisfaction with life as a whole and with specific life domains (Priebe *et al*. 1999), with mean scores between 1 and 7.

Six indicators of wellbeing, as identified in qualitative research with the client group (Schrank *et al*. 2013*b*), were measured. The Savouring Beliefs Inventory (SBI) is a 24-item scale assessing the ability to derive pleasure through anticipating upcoming positive events, savouring positive moments in the present and reminiscing about past positive experiences, with scores ranging between 1 and 7 (Bryant, 2003). The Integrative Hope Scale (IHS) is a 23-item scale that captures a comprehensive concept of hope and produces mean scores ranging between 1 and 6 (Schrank *et al*. 2012). The Rogers Empowerment Scale (RES) is a 28-item instrument measuring subjective feelings of empowerment resulting in mean scores between 1 and 4 (Rogers *et al*. 2010). The Rosenberg Self-Esteem Scale (RSE-S) contains 10 items measuring self-esteem with mean scores ranging between 0 and 3 (Blaskovich & Tomaka, 1991). The Sense of Coherence Scale (SCS) contains 29 questions to measure a person's global orientation to view their environment as comprehensible, manageable and meaningful. Mean scores range between 1 and 7 (Eriksson & Lindstrom, 2006). The Short Depression-Happiness Scale (SDHS) measures affect on a bipolar continuum between depression and happiness (Joseph & McCollam, 1993). It yields one overall score and two sub-scores which separately show depression and happiness. Mean scores range between 1 and 4 (Joseph *et al*. 2004).

In addition we used the Health of the Nation Outcome Scale (HoNOS), a 12-item measure of social disability covering a range of problem areas and sum scores ranging between 0 and 48 (Pirkis *et al*. 2005); the Brief Psychiatric Rating Scale (BPRS), an 18-item measure of psychiatric symptom severity with sum scores ranging between 18 and 126 (Overall & Gorham, 1988); and the Sociodemographics Form-Service User (SF-SU),

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a non-standardised measure modified from another RCT (Slade *et al*. 2011) recording sociodemographics, diagnosis and years using mental health services.

All scales, except for the PPI and SF-SU, were validated for, or have been used with, people with mental health problems, including psychosis. All measures, except for the BPRS and HoNOS, were participant-rated. Assessments lasted between 45 and 120 min.

Procedures

Participants were recruited between April and August 2013 from eight teams in one mental health service in South London, UK: two specialist psychosis community services holding registers of service-users interested in participating in research, five community mental health teams and one inpatient rehabilitation service. Letters about the WELLFOCUS Trial were sent to members of the research registers. Care-coordinators from the other teams were asked to refer potential participants to the research team. All participants were contacted via telephone, received information about the study and, having given assent, booked an interview for informed consent procedures and baseline measures. Randomisation was independently conducted after baseline, by the King's Clinical Trials Unit (registration number 053), in groups of 8 to 20 participants (as block randomisation representing multiples of 2 and 4 people). Follow-up interviews took place within 2 weeks of the intervention finishing. Assessors were not involved in therapy provision, but were not blinded to intervention status. Raters were changed between baseline and follow-up, but as all worked in the same research team, the resources required for adequate allocation concealment would have been disproportionate for a pilot study (Craig *et al*. 2008). Fidelity evaluation followed the framework of the NIHBCC Treatment Fidelity Workgroup, including the levels of provider training, treatment delivery and treatment receipt (Bellg *et al*. 2004). Detailed notes were taken at each session by the co-therapist and then independently rated by the research team using a fidelity scale specifically developed to assess the specific content of WELLFOCUS PPT. Qualitative process evaluation employing individual interviews and focus groups was undertaken with intervention group participants and therapists after the follow-up assessments.

Analysis

A proportion (21%) of the data was double-entered, with a concordance rate of 99.96%. Up to two missing items per questionnaire were pro-rated, and only one questionnaire (IHS) was excluded for one person due to more than two missing items. Normality of the data distribution was confirmed using the Shapiro–Wilks test, box-plots and Q–Q plots. Therefore parametric statistical methods were applied. Mean differences between baseline and follow-up and paired sample *t*-tests were calculated for all assessed variables. ANCOVA was used for intention-to-treat (ITT) analysis controlling for baseline score for all participants with complete data. Secondary analysis adjusted for therapy group to control for effect modification. Standardised effect size (Cohen's d) was calculated. Complier Average Causal Effect (CACE) analysis was conducted to assess the efficacy of the intervention among compliers on the primary outcome. The CACE model including baseline scores was fitted using the two-stage least squares estimation method. Compliance was defined as attending more than 50% of the sessions (i.e., 6 or more). To estimate feasibility and trial parameters for a definitive RCT, referral and consent rates, rates of intervention receipt, attendance and loss to follow-up were calculated. Logistic regression was used to explore the influence of process times on attendance. Samples sizes needed for a definitive trial (ANCOVA) were calculated using the means in the intervention group, pooled standard deviations and correlations between baseline and follow-up.

Qualitative process evaluation data from participants and facilitators were audio-recorded and transcribed verbatim and supplemented with researcher notes and feedback. Content analysis was applied, which identifies predefined entities of meaning from the data, i.e., specific categories designed to be mutually exclusive (Neuendorf, 2002). Qualitative analysis was conducted independently by two researchers to enhance reliability, with results compared and discrepancies resolved through discussion.

Results

Participants

The flow diagram for the 94 study participants is shown in Fig. 1.

Baseline participant characteristics are shown in Table 1. As expected, participant characteristics were balanced in the two arms after randomisation.

WELLFOCUS PPT was provided to six groups, and each group had an average of eight (range 4–10) participants. The median number of sessions attended was 7.

Objective 1: Testing trial procedures

Referral and consent rates

Forty-seven care-coordinators referred potential participants to the research. The mean overall consent rate

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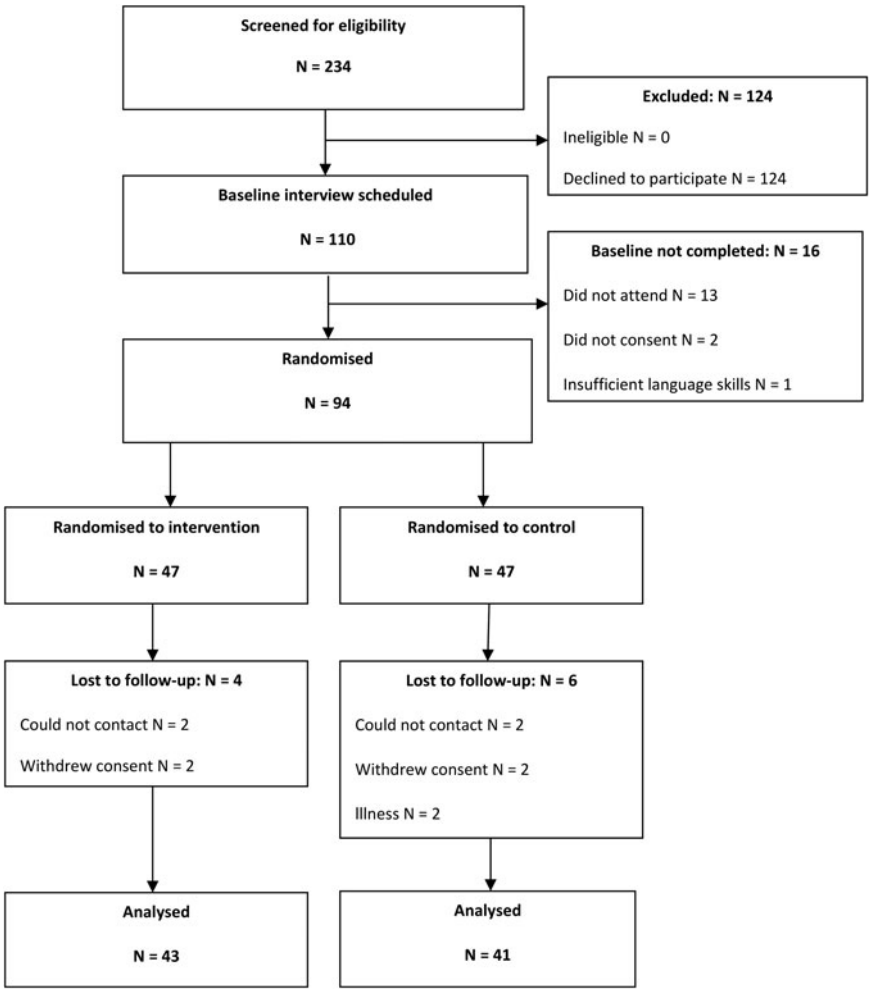

Fig. 1. Participant flow in the WELLFOCUS Trial.

was 40.2% (35.9% for those referred by care coordinators, and 81.8% for those contacted via research registers). For the 124 people who declined to take part in the study at initial contact, the most frequently given reason was dislike of group therapy ($N = 26$). Other reasons included: timing of the therapy ($N = 19$); location ($N = 12$); dislike of questionnaires ($N = 16$); no interest in PPT ($N = 13$); no need for therapy ($N = 5$); no experience of psychosis ($N = 1$); already doing another therapy ($N = 1$), and no reason provided ($N = 26$). Six participants who originally expressed interest could not be contacted again.

Allocation procedures

Feedback from participants on the process of randomisation was generally positive, with only two suggesting that randomisation was not fair and ways of dealing with unpreferred allocation should be discussed before randomisation. Mean time from referral to baseline assessment was 18.6 (S.D. 12.9) days and from baseline assessment to first group 11.7 (S.D. 4.2) days. Completer status was not predicted by waiting time (referral to assessment OR = 0.99, $z = -0.4$, $p = 0.69$, assessment to first group OR = 1.01, $z = 0.2$, $p = 0.87$). Four intervention group participants attended no sessions.

Attendance and loss to follow-up

Mean attendance rate was 54.2% (range 38–80%) sessions, and 26 (55%) of the 47 intervention group participants were completers. A total of 84 (89.4%) participants had baseline and follow-up data. The difference in the proportion of drop-outs between the two groups was not significant ($z = 0.669$, $p = 0.503$). Drop-outs did not differ significantly from non drop-outs in gender (chi^2), age, wellbeing or symptoms (*t*-tests) at baseline.

Reported reasons for non-attendance were mental or physical illness ($N = 5$), hospital/physician appointments ($N = 5$), being otherwise occupied ($N = 5$),

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Table 1. *Sociodemographic and baseline clinical characteristics (n = 94)*

		Intervention	Control
		Mean (S.D.)	Mean (S.D.)
Age		43 (11.0)	42 (11.5)
		n (%)	*n* (%)
Gender	Male	26 (55.3)	30 (63.8)
Ethnicity	White	21 (44.7)	23 (50)
	Non-white	26 (55.3)	23 (50)
Birth place	UK-born	29 (61.7)	27 (57.4)
Accommodation	Owned	8 (17.0)	4 (8.5)
	Rented	27 (57.4)	34 (72.3)
	Other	12 (25.5)	8 (17.0)
Relationship status	Single	39 (83.0)	42 (89.4)
	In partnership	8 (17.0)	5 (10.6)
Qualifications	None	5 (10.9)	2 (4.3)
	Secondary education (11–16 years)	11 (25.6)	16 (34.8)
	Further education (16–18 years)	11 (25.6)	12 (26.1)
	Higher education (18+)	12 (26.1)	10 (23.3)
	Relevant professional training	7 (15.2)	6 (13.0)
Employment	Working or studying	10 (21.3)	10 (21.3)
	Not working	37 (78.7)	37 (78.7)
		Mean (S.D.)	Mean (S.D.)
Years using mental health services		13 (11.0)	14 (11.0)
Warwick-Edinburgh Mental Well-being Scale (WEMWBS)		3.19 (.76)	3.00 (.89)
Manchester Short Assessment of Quality of Life (MANSA)		4.05 (.85)	4.14 (1.01)
Positive Psychotherapy Inventory (PPI)		3.58 (.73)	3.44 (.80)
Brief Psychiatric Rating Scale (BPRS)		30.70 (8.81)	33.57 (8.42)
Short Depression-Happiness Scale (SDHS)		2.29 (.69)	2.48 (.76)
Integrative Hope Scale (IHS)		4.02 (.79)	3.72 (.85)
Rosenberg Self-Esteem Scale (RSES)		2.24 (.64)	2.09 (.66)
Savouring Beliefs Inventory (SBI)		4.80 (1.22)	4.48 (1.02)
Rogers Empowerment Scale (RES)		2.74 (.32)	2.71 (.32)
Sense of Coherence Scale (SCS)		4.18 (1.05)	3.81 (1.11)
Health of the Nation Outcome Scale (HoNoS)		7.29 (5.05)	9.62 (5.19)

location ($N = 3$), transport costs ($N = 2$), family needs ($N = 2$), anxiety of attending group sessions ($N = 1$), delusions/voices preventing attendance ($N = 1$); disorganisation ($N = 2$), low mood and lack of motivation ($N = 2$), not getting on with other people and lack of enjoyment of the first session ($N = 1$), misunderstanding the nature of the study ($N = 1$) and not being reminded by hostel staff to attend ($N = 1$).

Fidelity assessment

Fidelity evaluation at the level of provider training revealed 100% attendance at therapist PPT training and 60.7% attendance at the monthly peer supervision. Qualitative analysis of therapist interviews suggested time constraints and location as the main reasons for non-attendance. Corresponding suggestions to improve attendance were choosing a convenient location and paying therapists. To ensure fidelity at the level of treatment delivery, therapists were requested to meet before each session with co-therapists to discuss the session content. Compliance with these pre-session meetings was 100%. Fidelity assessment at the level of treatment receipt revealed a 97% content coverage across all therapy groups.

Objective 2: Estimating effectiveness and informing sample size

Treatment effect

No adverse events were reported. Given the low rate of missing items in questionnaires with only one necessary exclusion of the IHS, reporting of all 84 participants with follow-up assessments is possible for all other scales. Raw data on change for all assessed variables are presented in Table 2.

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Table 2. *Changes from baseline to follow-up (n = 84, except for IHS n = 83)*

Measure	Group	Mean difference (CI)	*p*
WEMWBS	Control	0.15 (−0.10–0.41)	n.s.
	Intervention	0.26 (0.06–0.45)	0.010
MANSA	Control	0.11 (−0.07–0.30)	n.s.
	Intervention	0.34 (0.11–0.57)	0.004
PPI	Control	−0.02 (−0.15–0.11)	n.s.
	Intervention	0.20 (0.06–0.35)	0.000
BPRS	Control	0.78 (−1.16–2.72)	n.s.
	Intervention	−2.51 (−4.70–0.32)	0.026
SDHS	Control	−0.07 (−0.22–0.09)	n.s.
	Intervention	−0.24 (−0.45–0.03)	0.028
IHS	Control	0.19 (−0.02–0.41)	0.080
	Intervention	0.21 (0.00–0.42)	0.048
RSES	Control	0.05 (−0.07–0.18)	n.s.
	Intervention	0.19 (0.04–0.34)	0.016
SBI	Control	0.05 (−0.16–0.27)	n.s.
	Intervention	0.08 (−0.15–0.32)	n.s.
RES	Control	0.01 (−0.07–0.08)	n.s.
	Intervention	0.07 (−0.01–0.16)	0.079
SCS	Control	0.17 (−0.03–0.36)	0.088
	Intervention	0.24 (0.01–0.46)	0.040
HONOS	Control	−0.37 (−1.91–1.18)	n.s.
	Intervention	0.03 (−1.38–1.44)	n.s.

WEMWBS: Warwick-Edinburgh Mental Well-Being Scale, MANSA: Manchester Short Assessment, PPI: Positive Psychotherapy Inventory, BPRS: Brief Psychiatric Rating Scale, SDHS: Short Depression-Happiness Scale, IHS: Integrative Hope Scale, RSES: Rosenberg Self-Esteem Scale, SBI: Savouring Beliefs Inventory, RES: Rogers Empowerment Scale, SCS: Sense of Coherence Scale, HONOS: Health of the Nation Outcome Scale

ITT analysis found no significant effect of intervention group on the primary outcome of wellbeing (WEMWBS) at follow-up after adjusting for baseline scores ($p = 0.37$), and the effect size was small (Cohen's $d = 0.15$). Table 3 summarises ITT analyses for all measures.

Adjusting the model for therapy group minimally increased effect sizes for the BPRS ($F(1, 76) = 8.7$, $p = 0.004$, ES = 0.43), and SDHS depression ($F(1, 76) = 4.9$, $p = -0.03$, ES = 0.41) but did not lead to any more outcomes falling below the $p = 0.05$ significance level. In both models, the highest effect sizes were found for symptom severity (BPRS) and depression (SDHS depression), followed by wellbeing as measured by the PPI.

CACE analysis showed a non-significant positive association between the intervention and WEMWBS scores at follow-up ($b = 0.21$, $z = 0.9$, $p = 0.4$).

Outcome assessment and definitive sample size calculation

The exclusion due to missing data of only one of the 11 standardised outcome measures from only one participant indicates the measures are acceptable and understandable to the client group. Outliers were very rare, with most scales showing none, and MANSA, RES and PPI between one and four. All scales showed highly significant correlations between baseline and follow-up, with the strength of the correlation ranging from 0.58 (WEMWBS) to 0.83 (PPI). Other scales which showed significant change due to the intervention in any of the analyses had correlations of 0.83 (PPI), 0.71 (BPRS) and 0.65 (SDHS).

Based on the results of this study, the sample size for a definitive trial using the WEMWBS as the main outcome measure (at a power of 0.9 and allowing for 20% drop-out) would have to be 1462 in order to obtain a statistically significant result. Necessary sample sizes for those measures showing a significant result in the present study would have to be 125 for the BPRS, 161 for the PPI and 206 for SDHS depression.

Discussion

This is the first study to report a randomised controlled trial of PPT specifically adapted for people with psychosis. Results of the ITT analysis show a non-significant result for the primary and most secondary outcome measures, except for the BPRS, SDHS depression and PPI which showed significant improvements in the

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Table 3. *Intention to treat analysis (n = 84, except for IHS n = 83)*

Scale	Follow-up mean (S.E.)		ANCOVA	Effect size
	Control	Intervention		
n	*41*	*43*		
WEMWBS	3.24 (0.10)	3.36 (0.10)	$F(1, 81) = 0.8$, $p = 0.37$	0.15
MANSA	4.21 (0.10)	4.42 (0.10)	$F(1, 81) = 2.3$, $p = 0.13$	0.21
PPI	**3.48 (0.07)**	**3.72 (0.07)**	$\mathbf{F(1, 81) = 5.9, p = 0.02}$	**0.30**
BPRS	**33.23 (.98)**	**29.37 (0.96)**	$\mathbf{F(1, 81) = 7.8, p = 0.006}$	**0.42**
SDHS overall	2.34 (0.09)	2.13 (0.08)	$F(1, 81) = 3.0$, $p = 0.09$	0.29
SDHS happiness	2.91 (.10)	3.03 (.10)	$F(1, 81) = 0.6$, $p = 0.42$	0.16
SDHS depression	**2.60 (.10)**	**2.29 (.10)**	$\mathbf{F(1, 81) = 4.7, p = 0.03}$	**0.38**
IHS	4.04 (0.10)	4.11 (0.10)	$F(1, 81) = 0.3$, $p = 0.62$	0.08
RSES	2.21 (0.07)	2.37 (0.07)	$F(1, 81) = 2.9$, $p = 0.09$	0.23
SBI	4.65 (0.11)	4.75 (0.10)	$F(1, 81) = 0.4$, $p = 0.53$	0.09
RES	2.73 (0.04)	2.80 (0.04)	$F(1, 81) = 2.0$, $p = 0.16$	0.22
SCS	4.12 (0.10)	4.26 (0.10)	$F(1, 81) = 1.0$, $p = 0.32$	0.13
HONOS	8.53 (0.68)	8.14 (0.66)	$F(1, 81) = 0.2$, $p = 0.68$	0.07

WEMWBS: Warwick-Edinburgh Mental Well-Being Scale, MANSA: Manchester Short Assessment, PPI: Positive Psychotherapy Inventory, BPRS: Brief Psychiatric Rating Scale, SDHS: Short Depression-Happiness Scale, IHS: Integrative Hope Scale, RSES: Rosenberg Self-Esteem Scale, SBI: Savouring Beliefs Inventory, RES: Rogers Empowerment Scale, SCS: Sense of Coherence Scale, HONOS: Health of the Nation Outcome Scale.
Bold = significant differences.

intervention as compared to the control group at moderate effect sizes.

Objective 1: Testing trial procedures

Recruitment of 94 participants in a short timescale suggests that the intervention had face validity to the teams and individuals recruited. However, an overall consent rate of 40.0% may not be achievable in a definitive trial with representative random sampling. The randomisation process was well accepted and successful overall. Waiting times between referral and the start of therapy varied widely between individuals. However, this appeared not to affect acceptability as waiting times were unrelated to completer status.

The attendance rate of 54.2% might be regarded as rather low. However, poor attendance and completion rates are a known problem in intervention studies with people with severe mental illness. This is especially true for exploratory trials with less enforcement and monitoring of the intervention than in explanatory trials (Dunn, 2013; Ruggeri *et al*. 2013). WELLFOCUS PPT was specifically designed as a service-user friendly and non-mandatory offer to help increase wellbeing. Together with the 11-week duration of the group therapy and the moderately symptomatic and long-term service use characteristics of participants this may account for the attendance rate. Identified reasons for non-attendance suggest that attendance in a definitive RCT could be increased through specific support, including regular reminders, reassurance and discussing reasons for non-attendance.

The outcome evaluation strategy proved acceptable and feasible, and correlations between baseline and follow-up results can inform sample size calculations for studies with similar client groups. Fidelity assessment proved feasible and sensitive to deviations from fidelity parameters. Overall fidelity was high, indicating that provider training, treatment delivery and treatment receipt were reliably deliverable.

Objective 2: Estimating effectiveness and informing sample size

No significant effect of group was found on wellbeing as the main outcome. However, we detected a significant improvement on the BPRS, with a moderate effect size in the ITT analysis comparable to effect sizes found for CBT in this client group (Jauhar *et al*. 2014). The BPRS is a researcher-rated scale, which in this non-blinded study might be susceptible to detection bias. However, the likelihood of bias is reduced by the fact that equally strong effects were found on the patient-rated SDHS depression sub-scale. This may be interpreted as a triangulation to support the positive impact of WELLFOCUS PPT on symptomatology, particularly depression. Nevertheless, in a blinded definitive RCT sample sizes may need to be

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increased for observer rated measures to yield statistically significant results, as blinding is known to reduce effect size (Juni *et al*. 2001).

At least seven explanations might account for the lack of impact on wellbeing. First, WELLFOCUS PPT may be truly ineffective for increasing wellbeing. However, in this pilot study the sample size was not chosen to establish effectiveness, but for the primary purpose of testing trial procedures and reliably estimating the sample size for a definitive RCT (Lancaster *et al*. 2004; Thabane *et al*. 2010). Second, it may not be suitable for increasing wellbeing within a timeframe of 11 weeks in people with psychosis. This argument is supported by meta-analysis evidence showing that positive psychology interventions in general are more effective when administered over relatively longer periods of time (Sin & Lyubomirsky, 2009). However, controlled studies also showed that delivering PPT for a period as short as 6 (Parks-Sheiner, 2009) or 8 weeks (Ouweneel *et al*. 2013) can be sufficient to statistically significantly increase wellbeing in healthy people, and that 6 weeks are sufficient to increase wellbeing in people with substance abuse disorder (Akhtar & Boniwell, 2010). Third, are indications that standard PPT may be more successful when applied as individual therapy (Bolier *et al*. 2013). Similarly, the CBT literature mainly refers to individual rather than group work and where the latter has been used it has been less successful. It is possible that the same is true for WELLFOCUS PPT. Fourth, the WEMWBS may not be sufficiently sensitive to detect change in people with psychosis. Whilst one controlled intervention study applying the WEMWBS found it to be sensitive to change, the respective participants were taken from a waiting list. They can therefore be assumed to have been highly motivated, and most did not suffer from psychosis (Margrove *et al*. 2012). Fifth, like the concept of recovery (Slade *et al*. 2012), the concept of wellbeing is complex. There is no agreement in the literature on what it actually consists of (Schrank *et al*. 2013*a*). The particular changes in wellbeing potentially brought about by WELLFOCUS may not be captured by either the WEMWBS or the SDHS happiness sub-scale. By contrast, the PPI is also a measure of wellbeing and it showed borderline significant changes attributable to the intervention. The PPI was specifically developed to measure change following PPT. While this may make it more responsive to change due to a PPT intervention, it may conversely be a process, rather than an outcome, measure. Sixth, the study design which allowed all participants in the control group to receive any psychotherapeutic intervention may have diluted the trial's effect size. However, this is unlikely given the change detected on secondary outcome measures. Seventh, the diverse experience of trial therapists, the rather small amount of training they received, and their partly low compliance with supervision may have diminished the positive effect of the intervention. This argument is supported by research showing that not only therapist competence (Ruggeri & Tansella, 2011), but also experience and the amount of training can significantly influence trial results (Steel *et al*. 2012). However, therapists were highly qualified on entry into the study and the intervention itself relatively intensive. This pilot trial tested a novel intervention for which training was not yet available. A future definitive RCT can build on the experience from this trial to inform therapist training and enforce attendance of supervision.

Strengths and limitations

As this study is the first to evaluate a new intervention, it is positioned as a pilot trial according to the MRC framework for the development and evaluation of complex interventions (Craig *et al*. 2008). Limitations include the non-random sampling, the use of clinical instead of research diagnoses, unblinded outcome evaluation, the use of TAU instead of an active comparison group, and non-monitoring of other psychological interventions. Given that this was a group based intervention, more exploration of group cohesion and other group process measures is also warranted as a possible intervening variable and should be a focus of future research. A significant proportion of participants were non-white. While all components of WELLFOCUS PPT were developed in the same culturally diverse population and are hence sufficiently culturally adaptable to serve such a diverse participant group, further exploration of cultural or religious implications for specific components, such as the understanding of forgiveness, are worth investigating in future research.

Conclusions

This study provides initial evidence on the likely feasibility and acceptability of WELLFOCUS PPT in the client group of people with psychosis. However, more work is needed to optimise its effectiveness before a definitive RCT can be recommended. Initial results from the qualitative process evaluation of this pilot study suggest particularly useful components (Brownell *et al*. 2014) and will allow further optimisation of the intervention manual. WELLFOCUS PPT may be viable for reducing overall symptom severity and specifically depression. Comorbid depression is a known challenge in the treatment of people with psychosis, affecting about 50% of people with

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schizophrenia (Buckley *et al*. 2009). The favourable effect of WELLFOCUS PPT on depressive symptoms needs to be evaluated further, with specific attention to including research diagnoses and establishing the causal pathway of action. Ways of supplementing the effect on symptoms in general are worth considering in future research, including for example, a choice or combination of individual and group work, or supplementing classic individual CBT with group WELLFOCUS PPT. How to select those participants who are most likely to respond also remains an important question for future research. In addition, a specific measurement challenge remains: how best to assess wellbeing. Our two wellbeing measures showed very different responsiveness to the intervention: WEMWBS did not change while the PPI consistently showed improvement. While a wide range of instruments suggested to measure wellbeing exist, only few have established sensitivity to change, let alone in samples of people with psychosis (Schrank *et al*. 2013*d*). Further research is needed to establish whether measuring wellbeing is a technical problem requiring the rigorous development and evaluation of new measures, or a conceptual problem caused by low validity in the construct of wellbeing (Shepherd, 2014). This may include the exploration of sensitivity to change in existing measures of wellbeing or related concepts such as hope. In either case, the goal of supporting individuals to live well with psychosis remains.

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Statement of interest

None.

Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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