A Randomised Controlled Pilot Study of Experience Focussed Counselling with Voice Hearers.

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Abstract

Background: There is a need for improved psychosocial interventions for distressed voice hearers.

Aims: To evaluate a novel approach to hearing voices: Experience Focussed Counselling (EFC) aka Making Sense of Voices.

Study design and methods: 12 voice hearers were randomly assigned to a 44-week EFC or Treatment As Usual intervention as part of a pilot study design.

Results: At the end of intervention EFC showed clinically large treatment effect improvements on the Brief Psychiatric Rating Scale – Expanded Version psychotic symptoms (Cohen's d=1.6) and overall psychopathology domains (d=1.3), and the Psychotic Symptom Rating Scales voices (d=1) and delusions (aka non-shared reality) (d=1) scales. EFC voice hearers also felt more able to do first trauma disclosures (n=4) than TAU group voice hearers (n=1).

Discussion: EFC improvements may have been related to the focus on reducing voices related distress. EFC holds some promise as a safe and effective intervention for voice hearers, with possible improvements in general psychopathology, psychosis, voices, and non-shared reality (aka delusions) related distress. This will need replicating in more powerful studies.

Keywords: hearing voices, psychosis, schizophrenia, Making Sense of Voices, Experience Focussed Counselling (EFC), randomised controlled trial (RCT), Hearing Voices Movement

Introduction

The need for a change in approach to the way distressed voice hearer(s) (VH) experience mental health services remains strongly supported by VH themselves, especially via the fast growing international Hearing Voices Movement (HVM) (Corstens, Longden, McCarthy-Jones, Waddingham & Thomas, 2014).

Short- and long-term side-effects of antipsychotic medication, including higher mortality rates (Aderhold & Stastny, 2007), and atypical antipsychotics only producing 18% better clinical response rates than placebo (Leucht, Arbter, Engel, Kissling & Davis, 2009) challenge the current dominance of medicalised approaches in routine psychiatric provision. Whilst a small majority recover clinically from schizophrenia, it remains unclear what helps in this process. A difficult to measure personal process of recovery appears more meaningful though necessitates a paradigm shift in psychiatric service provision (Slade, Amering & Oades, 2008; Dillon, Johnstone & Longden, 2012). An approach like CBT in Psychosis (CBTp) is currently modest in effectiveness (Wykes, Steel, Everitt & Tarrier, 2008). There is thus an on-going need to improve recovery rates and personal experience of recovery in current psychiatric provision.

Importantly, the individualised approach of the HVM, Experience Focussed Counselling (EFC) aka Making Sense of Voices (Romme & Escher, 2008), remains largely absent from mainstream mental health services. This may in part be the result of EFC not claiming to be a standardised or manualised intervention, as well as the use of less traditional sources of evidence (Schnackenberg & Martin, 2014). These contain primarily anecdotal stories of personal recovery (Romme, Escher, Corstens, Dillon & Morris, 2009); a self-selecting transdiagnostic sample of n=100 using aspects of the Making Sense of Voices approach (Corstens & Longden, 2013); and a convenience sample of n=27 finding beneficial effects in an anxiety-depression domain (Casstevens, Cohen, Newman, & Dumaine, 2006), using a workbook (Coleman & Smith, 1997).

This study therefore set out to evaluate a pilot randomised controlled trial (RCT) of EFC to highlight important issues of feasibility and safety for future research designs.

Qualitative results of the overall mixed-methods design were considered separately in line with a conceptual triangulation approach (Guest, MacQueen & Namey, 2012).

Methods

Design

Treatment As Usual (TAU) was compared with EFC in routine psychiatric settings over a period of 44 weeks, a practice-based estimate of the time needed to potentially complete an EFC process. The overall research aims focussed on evaluating EFC's 1) applicability across diagnoses; 2) its relative value in improving primary and secondary clinical distress and recovery measures; 3) its ability to help understand and work on unresolved problems in a person's life. The study concentrated on the feasibility of recruitment, randomisation, retention, assessment, study design methods, and novel EFC interventions employed. Some initial hypothesis testing provided early indications regarding the safety, efficacy and effectiveness of EFC (Arain, Campbell, Cooper & Lancaster, 2010).

Participants

Inclusion criteria reflected concerns about using scientifically contested diagnostic concepts such as schizophrenia (Bentall, 2009), and the fact that voice hearing is experienced across diagnoses (Aleman & Laroi, 2008). A symptom, or experience, focus was used instead. Using the language of experience instead of symptom, voice hearing instead of auditory hallucination, and non-shared reality instead of delusions respectively, was also expressing the non-pathologising paradigm of the HVM ethos (Romme, 2009).

Participant inclusion criteria were:

- 1) 18 65 years of age
- 2) Voice hearing distress levels of a ≥4 severity rating on the Brief Psychiatric Rating Scale – Expanded Version (BPRS-E) hallucination item, in line with needs-based psychosis definitions (Bak et al., 2003).
- 3) VH did not have to identify themselves as voice hearers (Romme & Escher, 2008). Experiences had to be audible, without a clear external source (Haddock, 2009).
- 4) Any or no psychiatric diagnosis.
- 5) No alcohol or drug abuse in the past 3 months.
- 6) No organic brain disease or diagnosis of dementia.
- 7) IQ over 70.

Recruitment

Recruitment of smaller numbers to complex psychosocial interventions like CBTp (Lynch, Laws & McKenna, 2010) or Open-Dialogue (Seikkula, Alakare & Aaltonen, 2011) is not unusual.

A 4-year period of varied recruitment efforts by the first author saw two psychiatric services provide a mixed sample: the St Ansgar gGmbH in the North of Germany; and the Pfalzklinikum in the South West of Germany. Following a brief study information session by the first author, local mental health professionals (MHP) were asked to inform and invite potentially interested VH. VHs' fear of medication increases and extensions of psychiatric support should they talk openly about voices, as well as the randomised design, hampered potential participation.

Sampling

N=42 VH were screened, n=29 met inclusion criteria, n=22 finally agreed to continue with the study following randomisation. Reasons given by the n=7 VH not to continue with the study following randomisation, were: 1) a fear of not being discharged if they talked about voices (n=1); 2) only wanting to take part in the opposite groups to the respective groups they had been randomised into (n=2 and n=1 respectively); 3) dying of a heart attack, despite being below 30 years of age (n=1); 4) focusing on a new relationship instead (n=1); 5) no reasons given (n=1).

Interventions

Both groups continued to have access to all normal TAU interventions. MHP were asked to spend a flexible 45 – 60 minutes one-to-one time with the VH on 2 – 3 occasions per month to allow for clinical variations and to control for non-specific intervention effects (Valmaggia, van der Gaag, Tarrier, Pijnenborg & Sloof, 2005). The main difference between the groups was therefore the respective focus of one-to-one conversations. The EFC group focussed on EFC interventions and the TAU group on providing generic support as described below.

EFC

EFC denotes a mutual process of making sense of the voice hearing experience within the person's life context (Corstens & Longden, 2013), and of supporting the VH in learning to better deal with the experience as part of a recovery process (Corstens, Escher & Romme, 2009). In EFC voices also express a normal human experience which at best needs to be given

the chance to be socially and individually emancipated (Romme, Honig, Noorthorn & Escher, 1992) but must certainly not be cured. Pathologising language would therefore be inappropriate in this context (Romme, 2009).

Participating MHPs were given written guidance based on the theory by Romme & Escher (2008), additional HVM practice-based insights (Corstens et al., 2014) and the practice experience by the first author of the study. They were asked to engage in the sequential use of EFC tools such as the Maastricht Interview, Report and Construct, alongside the development of HVM-suggested coping strategies, including voice dialogue (Corstens, Longden & May, 2012). These tools, when employed creatively and yet in a structured manner, aid the process of bringing order, life context, and increasing calmness to what can often be experienced as a very chaotic and anxiety provoking experience of voice hearing. Attempting to answer 1) who(m) and 2) what problems the voices represent within a summarised outline of life context, completes the process as part of a Construct development (Corstens, Escher & Romme, 2009).

Importantly, the EFC approach, whilst frequently uncovering traumatic life connections to voices (Corstens et al., 2014), is marked by an attitude of working within the explanatory system of the VH. The process should also be VH-led and ideas or processes should not be imposed (Romme & Escher, 2008).

Training in EFC

EFC delivering MHP were trained in the application of EFC tools via a 3-level progressing training programme (total of 6 days) which ran alongside the first 6 months of the study with three months in between levels. Individual interventions started following the first training level.

In line with HVM principles, EFC group VH could and did take part in some or all of the EFC training at n=5, n=6, n=5 for the three levels respectively. A predictably varied attendance amounted to m=46.35% of the total time across workshops. MHP's EFC taught material comprehension was tested via 10 and 11 items multiple choice tests, including theory and a practice video at the end of respective training levels. Excellent ($k\ge0.75$) (Coolican, 2009) Cohen's KAPPA interrater reliability at k=0.96; k=0.93; and k=0.92 were reached, thus contributing to intervention fidelity.

EFC training was delivered by three experienced EFC trainers of the EFC Institute (EFC training organisation based in Germany), including a recovering VH. The first author of this

article was one of the EFC trainers (having been trained and supervised by Coleman, Corstens, Romme & Escher among others) with several years experience of providing EFC supervision and training. He had also been applying EFC in a variety of routine acute and community mental health settings since the year 2000.

TAU

TAU generally comprised of antipsychotic medication, general rehabilitative life skills support and techniques for the distraction from voices or challenging beliefs, thus representing a classic mainstream biological model psychiatric approach.

Counsellors/Accompaniers

Using the term counsellor or accompanier highlighted that therapy is not what EFC is about, even if it may have therapeutic or distress alleviating benefits. The interventions were delivered by experienced staff (paedagoges, nurses, psychologists, social workers). They were all new to EFC. EFC supervision ensured intervention fidelity and was offered via one-to-one and group supervision by the first author. It amounted to an average of m=8.57 minutes/week (s.d.=4.37) per MHP.

Ethical Approval

Informed consent of participants was obtained prior to the study. University of the West of Scotland and local ethical approvals were gained between June 2011 and December 2012. The study took place between August 2011 and January 2014.

Randomisation

Participants were randomised in blocks of 2 (1 control group; 1 intervention group). Thus, where possible, every participating MHP had one person to support in the intervention and one in the control group respectively, to minimise therapist-specific effects (Valmaggia et al., 2005).

Outcome Measures

Assessment periods covered the last 7 days respectively. Apart from satisfactory to good reliability and validity criteria, choice of primary and secondary outcome measures aimed to afford comparability with related studies and address current discussions on recovery and

psychosis, as well as the hypothesised potential impact of voice hearing distress on other domains or their relevance in influencing voice hearing distress (Romme & Escher, 2008).

Primary Measures

The BPRS-E (Ventura et al., 1993) is a general psychopathology 24-item, 1-7 point Likert scale, outcome measure, with no-predetermined subscale structure. Ratings of ≥ 4 are considered clinically relevant. To determine which factorial solution to use in the analysis of this study's results, a review confirmed its use in psychosis related research and identified the 4-factor solution by Velligan et al. (2005), with its trans-diagnostic focus, which included similar diagnoses to this study's sample.

Voice hearing dimensions were addressed with the Psychotic Symptom Rating Scales (PSYRATS) auditory hallucinations (voices) scale (Haddock, McCarron, Tarrier & Faragher, 1999; Haddock, 2009), which has been commonly used in VH related research. It consists of 11 items with ratings from 0 (no distress) – 4 (very distressed) and there are no fixed clinical cut off points.

The Questionnaire about the Process of Recovery (QPR) (Neil et al., 2009) is a 22-item self-completion scale, consisting of an interpersonal and intrapersonal subscale. It was jointly developed with people in recovery from psychosis experiences. Scoring ranges from 0 (disagree strongly) – 4 (agree strongly) with higher scores indicative of greater recovery.

Secondary Measures

As a result of the word limit, only clinically significant and relevant findings could be included in this article.

Rater Training

Raters were compared to gold-standard ratings and trained prior to the study to excellent $(k \ge 0.75)$ (Coolican, 2009) inter-rater agreements on the BPRS-E (k=0.90), the PSYRATS (k=0.82), and the SAI-E (k=0.95).

Translation Process

Employing a panel of experts process (Harkness, 2003), the main author of this study translated both small necessary updates (two primary measures) and all of the remaining scales completely, apart from the already translated secondary HADS and HAq-II measures.

Statistics

Data Collection

There were three post-baseline assessment points, coinciding with the points in time prior to the respective EFC training workshops II (3 months), and III (6 months) and at the end of treatment at 44 weeks. Assessments were conducted by the respective MHP delivering the intervention, as identifying and engaging in the full extent of the voice hearing experience was best considered possible within a trusted, non-pathologising relationship (Romme, 2009). Whilst blinding is difficult to achieve in reality as language used might unintentionally betray VH group allocation (Turkington, Kingdon, & Weiden, 2006), it has the advantage of reducing potential raters' bias and social desirability responses by participants, as evidenced by lowered effect sizes in blinded CBTp trials (Wykes et al., 2008). Given the feasibility focus of this study, participant safety and trust appeared to outweigh study design purity at that stage, and a non-blinding process was therefore chosen.

Statistical Analyses

All statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS) 20 and 22, alongside Microsoft Excel for effect size and sample size calculations.

Data Analyses Employed

Although the small sample size would only allow for indications rather than the ability to provide firm conclusions on evidence, statistical tests would allow for an indication whether bigger samples might indeed achieve a treatment effect in future studies. A mixed 2 (group: EFC, TAU) x 4 (time: baseline, 3-months, 6-months, 44-weeks) repeated measures Analyses of Variance (ANOVA) tested for overall significance (α =0.05). Treatment effect sizes were calculated using Cohen's d ((mean difference of experimental group – mean difference of control group)/pooled s.d) (McGough & Faraone, 2009), supported by confidence interval calculations (Howell, 2010) and complemented by paired t-tests.

Missing data were followed up and a Complete Cases Analysis was conducted.

Results

Engagement in Study

Only n=12 completed all 3 post-baseline assessment point measures, due to staff shortages (n=4), staff sickness (n=2), moving house (n=1), no benefits felt (n=3 TAU clients).

Independent *t*-tests of baseline outcome and demographic measures comparing completers with non-completers, and the *n*=5 participants/group not completing their respective intervention group confirmed attrition bias was kept low (Dumville, Torgerson & Hewitt, 2006).

One EFC group VH moved away before completing the final set of self-completion scales, leading to a reduction of n=1 in these scales.

Due to staffing and sickness problems, one-to-one time amounted to m=10.21, s.d.=5.64 (EFC group) and m=9, s.d.=17.10 (TAU group) minutes/week, instead of the suggested minimum m=20.78 minutes/week.

Engagement in EFC was characterised by an initial hesitation by some VH participants, as they feared increases in medication, hospital stays, a pathologisation of their experiences, and looking more closely at anxiety provoking and personal experiences. However, both MHP and VH reported benefiting from, and appreciating, this way of engaging as very relevant.

Sample Description

A series of independent *t*-tests of outcome measures at baseline between EFC and TAU group confirmed a largely successful randomisation. Participating clients were not significantly different in terms of age, gender, length of continuous psychiatric contact, total admissions, primary diagnosis, time since diagnosis (table 1), ethnicity, marital, employment, housing status, first psychiatric contact, last year's number of admissions, and secondary diagnosis (*unpublished data*). Number of antipsychotics and Chlorpromazine equivalent doses were a lot higher than recommended for maintenance treatment (table 1).

As a next step, analysing potential improvements would help to address EFC effectiveness (research question 2) but also EFC's potential trans-diagnostic applicability (research question 1).

Table 1 EFC and TAU background characteristics

Primary Outcomes

The time x group interaction effect was significant in the BPRS-E psychosis subscale (F(3,30)=5.37, p=.004, ES=.349) and, using the Greenhouse-Geisser Epsilon, nearly significant in the BPRS-E total scale (F(1.75,17.51)=3.50, p=.058, ES=.259).

Paired *t*-test and treatment effect size analyses (table 2) confirmed directional a priori hypotheses of greater EFC improvements and the findings of the ANOVA. The BPRS-E total scale highlighted statistically significant within EFC group improvements at the 3-months (p=.012 (one-tailed)) and 44-weeks (p=.013 (one-tailed)) time points. Similar improvements were again noted in the BPRS-E psychosis factor at the 3-months (p=.009 (one-tailed)) and the 44-weeks (p=.012 (one-tailed)) time points. These findings were further substantiated by large (d≥0.8) treatment effect size improvements (range of d=0.9 – d=1.7) for both scales throughout the study. Of note were also the EFC group treatment effect improvements on the BPRS-E anxiety and depression domain, which were large (d=1.2) at 3-months, and medium (d=0.6) at 44 weeks. The BPRS-E negative symptoms and activation factor showed no clinically relevant trend ($unpublished\ results$). Importantly, the PSYRATS voices scale steadily improved towards a large treatment effect at the end of the study (d=1.0). Interestingly, the QPR revealed an increasing not significant endorsement of intrapersonal aspects of recovery in the EFC group, whilst the TAU group tentatively suggested a need for greater interpersonal aspects of recovery across time points ($unpublished\ results$).

Table 2 Primary outcomes

Secondary Outcomes

At the end of treatment, there were large EFC group treatment effect improvements on the PSYRATS delusions (aka non-shared reality) scale (d=1.0) (with n=4 for both groups); the MHLC-C (locus of control) chance subscale (Wallston, Stein & Smith, 1994) (d=1.2); as well as small reductions (d=0.4) in Chlorpromazine equivalent use and less days spent in hospital than the TAU group (d=0.6). 5 EFC participants completed the Maastricht Interview, 4 the Maastricht Report, and 2 the Maastricht Construct. Importantly, 57% (n=4) in the EFC group and only 20% (n=1) in the TAU group disclosed traumatic experiences for the first time.

Discussion

Limitations

The small sample size, the pilot nature of this study, the use of measuring tools not yet validated in German and the lack of blinding were obvious limitations of the study. Findings can thus only provide some initial support towards EFC being applicable across diagnoses, and effective in improving general psychopathology, psychosis, voice hearing related (table

2), and non-shared reality distress, as well as the lessening of the locus of control chance element. The use of frontline practitioners, provided early evidence of EFC's potential value in routine psychiatric practice settings in contrast to other interventions' (i.e. CBTp) often more artificial research designs (Thomas, 2015).

As this study had controlled for counsellor-specific factors, non-specific intervention effects, and antipsychotic medication use, a more likely explanation for EFC improvements, also supported by the qualitative study (*unpublished results*), which, too, addressed the above stated research aims, might be the EFC group's focus on reducing voices related distress with a potential effect on locus of control and general psychopathology, too. Encouragingly, relatively high baseline distress levels and being part of long-term rehabilitative settings did not prevent positive engagement and improvements.

Importantly, EFC improvements took place despite a higher number of first trauma disclosures, suboptimum provision of one-to-one support and a minimum level of supervision only.

Feasibility

Given that no EFC group VH left the study or relapsed as a result of the intervention and the processes of randomisation, retention, assessment, and EFC intervention went largely smoothly, the feasibility and safety of a full-scale, comparable study set up RCT was supported by this pilot study (Arain et al., 2010). Including 6-months or more follow-ups, to measure longevity of effects, would be important. VH fears of participation could be addressed via written agreements with research sites to not automatically react with medication or hospital admissions should VH open up about their experience. The employment of research assistants could ensure a greater time commitment and thus more success in recruitment, the completion of assessments, and possible blinding.

Clinical Implications

This study provided an early promise of voice hearing, psychosis, non-shared reality and general psychopathology distress reducing effects of EFC, supported by a potential for EFC to facilitate trauma disclosure and the lessening of the chance element, despite psychotic spectrum diagnoses. Importantly, both research sites expressed interest in rolling out EFC further. These results thus support further large-scale RCTs and EFC's potential application in psychiatric practice.

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Table 1: EFC and TAU background characteristics

Variable	EFC (<i>n</i> =7)	TAU (<i>n</i> =5)	p (2-tailed): EFC vs TAU
Age [mean (s.d.)]	44.14 (9.49)	40.20 (11.32)	t=.656, df 10, p=.527
Gender [<i>n</i> (%)]			x^2 =.010, df 1, p =.921
Female	3 (42.86)	2 (40.00)	
Male	4 (57.14)	3 (60.00)	
Continous psychiatric contact,	18.29 (10.00)	18.20 (9.55)	t=.015, df 10, p=.988
years [mean (s.d.)]			
Total admissions $[n \text{ (s.d.)}]$	11.14 (7.31)	26.00 (19.01)	t=-1.66, df 4.85, p=.159
Primary diagnoses [n (%)]			x^2 = .779, df 1, p =.377
Schizophrenia	6 (285.71)	5 (100.00)	
Schizoaffective disorder	1 (14.29)	0 (0)	
Time since diagnosis, years	18.00 (7.66)	18.60 (9.21)	<i>t</i> =123, <i>df</i> 10, <i>p</i> =.904
[mean (s.d.)]			
Mean number antipsychotics	2	2.4	
Chlorpromazine equivalent	958.78 (516.50)	915.50 (500.84)	t=.145, df 10, p=.888
dose* [mean in mg (s.d.)]			

^{*}Chlorpromazine equivalents were calculated using biomedcentral (Biomedcentral, 2013a;b) as a primary source, then Woods (2011) followed by Janssen, Weinmann, Berger & Gaebel (2004).

Table 2 – Primary Outcomes (Mean, standard deviation, within-group significance, treatment effect size)

Outcome measure			3-months Mean (s.d.)		6-months Mean (s.d.)		44-weeks Mean (s.d.)		p (2-tailed) within-groups		d (treatment effect size) (95% Confidence Intervals)			
									3- months	6- months	44- weeks	3-months	6-months	44-weeks
BPRS-E														
Total														
EFC (n=7)	61.86	(15.08)	45.86	(12.77)	51.14	(12.81)	49.29	(12.31)	.024*+	.166	.025*+	1.7(0.32-3.06)	0.9(-0.31-2.12)	1.3(0.04-2.61)
TAU (n=5)	56.20	(16.16)	60.00	(16.31)	59.60	(15.69)	56.60	(12.76)	.191	.486	.898			
BPRS-E		•		•		•		•						
Psychosis														
EFC	14.43	(4.50)	8.00	(4.83)	9.00	(4.87)	9.57	(4.79)	.018*+	.046	.023*+	1.5(0.17-2.82)	0.9(-0.37-2.05)	1.6(0.24-2.93)+
TAU	12.00	(2.92)	12.80	(4.60)	13.40	(4.88)	13.80	(3.70)	.374	.338	.221			
BPRS-E														
Anx./Depr.														
EFC	12.43	(4.39)	10.29	(3.45)	11.29	(3.40)	9.43	(3.60)	.264	.550	.184	1.2(-0.11-2.40)	0.3(-0.83-1.49)	0.6(-0.55-1.81)
TAU	11.00	(5.24)	13.80	(2.28)	11.40	(2.88)	11.00	(3.81)	.154	.840	1.00			
PSYRATS		•		•										
Voices														
EFC (n=7)	29.29	(4.86)	24.43	(7.28)	25.71	(8.90)	23.79	(11.63)	.190	.452	.122	0.1(-1.01-1.29)	0.4(-0.78-1.53)	1(-0.28-2.16)
TAU (n=5)	26.00	(10.49	22.20	(15.82)	26.00	(10.12)	26.70	(10.88)	.223	1.00	.578	,		·

Anx./Depr. – anxiety and depression factor; BPRS-E – Brief Psychiatric Rating Scale – Expanded Version 4.0; *d* – Cohen's effect sizes (1992): 0.2 – small; 0.5 – medium; 0.8 – large); EFC – Experience Focussed Counselling; *n* – sample size; *p* – statistical significance (set at 0.05); Psychosis – psychotic or positive symptoms factor; PSYRATS – Psychotic Symptom Rating Scales; s.d. – standard deviation; TAU – Treatment As Usual; Total – total scale – denoting overall psychopathology; Voices – voices aka auditory hallucinations scale; * - Achieved one-tailed significance for a priori directional hypotheses despite Bonferroni Correction; + - Achieved one-tailed power of *β*≥0.80;