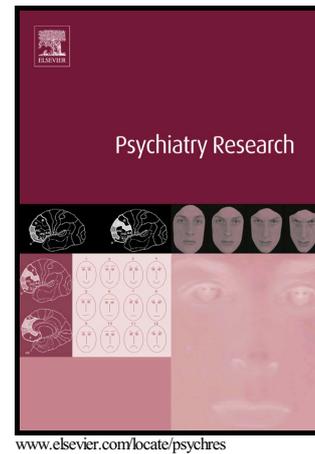


Author's Accepted Manuscript

Cognitive Therapy for Internalised Stigma in People Experiencing Psychosis: A pilot randomised controlled trial

Anthony P. Morrison, Eilish Burke, Elizabeth Murphy, Melissa Pyle, Samantha Bowe, Filippo Varese, Graham Dunn, Nicola Chapman, Paul Hutton, Mary Welford, Lisa J. Wood



PII: S0165-1781(16)30588-1
DOI: <http://dx.doi.org/10.1016/j.psychres.2016.04.024>
Reference: PSY9586

To appear in: *Psychiatry Research*

Received date: 8 June 2015
Revised date: 2 March 2016
Accepted date: 10 April 2016

Cite this article as: Anthony P. Morrison, Eilish Burke, Elizabeth Murphy, Melissa Pyle, Samantha Bowe, Filippo Varese, Graham Dunn, Nicola Chapman, Paul Hutton, Mary Welford and Lisa J. Wood, Cognitive Therapy for Internalised Stigma in People Experiencing Psychosis: A pilot randomised controlled trial, *Psychiatry Research* <http://dx.doi.org/10.1016/j.psychres.2016.04.024>

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and a review of the resulting galley proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

**Cognitive Therapy for Internalised Stigma in People Experiencing Psychosis: A pilot
randomised controlled trial**

**Anthony P. Morrison^{a, b*}, Eilish Burke^{a, b}, Elizabeth Murphy^b, Melissa Pyle^{a, b}, Samantha
Bowe^b, Filippo Varese^a, Graham Dunn^c, Nicola Chapman^b, Paul Hutton^d, Mary
Welford^b, Lisa J. Wood^{a, e}**

^a School of Psychological Sciences, University of Manchester, Manchester, United Kingdom

^b Greater Manchester West NHS Mental Health Foundation Trust, Manchester, United Kingdom

^c Biostatistics Research Group, School of Medicine, University of Manchester, Manchester, United Kingdom

^d University of Edinburgh, Edinburgh, United Kingdom

^e North East London NHS Foundation Trust, London, United Kingdom

* Corresponding author: tony.morrison@manchester.ac.uk

Abstract

We aimed to evaluate the feasibility of Cognitive Therapy (CT) as an intervention for internalised stigma in people with psychosis. We conducted a single-blind randomised controlled pilot trial comparing CT plus treatment as usual (TAU) with TAU only.

Participants were assessed at end of treatment (4 months) and follow-up (7 months). Twenty-nine participants with schizophrenia spectrum disorders were randomised. CT incorporated up to 12 sessions over 4 months (mean sessions = 9.3). Primary outcome was the Internalised Stigma of Mental Illness Scale – Revised (ISMI-R) total score, which provides a continuous measure of internalised stigma associated with mental health problems. Secondary outcomes included self-rated recovery, internalised shame, emotional problems, hopelessness and self-esteem. Recruitment rates and retention for this trial were good. Changes in outcomes were analysed following the intention-to-treat principle, using ANCOVAs adjusted for baseline symptoms. There was no effect on our primary outcome, with a sizable reduction observed in both groups, but several secondary outcomes were significantly improved in the group assigned to CT, in comparison with TAU, including internalised shame, hopelessness and self-rated recovery. Stigma-focused CT appears feasible and acceptable in people with psychosis who have high levels of internalised stigma. A larger, definitive trial is required.

Keywords

cognitive therapy; stigma, psychosis, schizophrenia

1. Introduction

Goffman originally described stigma as ‘an attribute which is deeply discrediting’ and as ‘an undesired differentness’, and described internalised stigma as identification with a negative stereotype (Goffman 1963). Social cognitive models suggest that stigma is comprised of cognitive (stereotypes and prejudice), affective (prejudice) and behavioural (discrimination) components which drive and maintain stigma (Corrigan, Kerr et al. 2005), and stigma has been defined as a concept which incorporates, labelling, stereotyping, separation, status loss and discrimination (Link and Phelan 2001). Stigma and discrimination can have negative effects on mental wellbeing in many ways, and people with a psychiatric diagnosis are seen as dangerous, unpredictable, different, and unlikely to recover (Crisp, Gelder et al. 2000; Crisp, Gelder et al. 2005; Wood, Birtel et al. 2014). The extent to which psychosis is stigmatised has been widely recognised and it is one of the most stigmatised mental health problems (Thorncroft, Brohan et al. 2009; Brohan, Elgie et al. 2010). People with psychosis are often stereotyped as dangerous and unpredictable and the public express the greatest desire for increased social distance from people with psychosis (Angermeyer and Matschinger 2003; Angermeyer and Matschinger 2003; Lincoln, Arens et al. 2008), and stigma has been described by service users as more disabling than schizophrenia itself, resulting in a second ‘illness’ (Finzen 1996). Service users have identified stigma, in particular media images, as a negative influence on suicide, and have identified stigma as a priority in suicide prevention (Eagles, Carson et al. 2003). Other psychological conditions such as depression, social anxiety and low self-esteem may occur as a direct consequence of stigma (Birchwood, Mason et al. 1993; Birchwood, Trower et al. 2007; Corrigan and Watson 2007).

It has been suggested that stigma has two major dimensions; public stigma and self-stigma (Corrigan and Watson 2002). Public stigma is said to incorporate three components; negative attitudes, beliefs/stereotypes, and discriminatory behaviour. Self-stigma or internalised stigma is the internalisation of these components, defined as. “the internalisation of shame, blame, hopelessness, guilt and fear of discrimination associated with mental illness”(Corrigan and Watson 2002) . A high proportion of service users with a diagnosis of schizophrenia report moderate to high levels of internalised stigma (Brohan, Elgie et al. 2010). A recent systematic review found a strong negative relationship between internalised stigma and a range of psychosocial variables including hope, self-esteem, empowerment and adherence with treatment, and a strong positive relationship with psychiatric symptoms (Livingston and Boyd 2010). Stigma associated with psychosis can: discourage people from seeking help (Thornicroft 2007), which may delay treatment; lead to social isolation, which can exacerbate problems (Link, Struening et al. 1997; Thornicroft, Brohan et al. 2009); act as a mechanism of social exclusion, which hampers recovery (Link, Struening et al. 1997; Link, Struening et al. 2001; Ritsher and Phelan 2004); reduce employment and education opportunities (Link, Struening et al. 1997; Thornicroft, Brohan et al. 2009); result in poorer physical healthcare, suicidality, and higher mortality rates (Thornicroft, Rose et al. 2007).

In the UK, the NICE Guidelines for Schizophrenia prioritise the reduction of stigma (National Institute for Health and Care Excellence 2014) and the World Health Organisation’s early psychosis declaration, has a primary objective to ‘Challenge stigmatising and discriminatory attitudes so that young people are not disadvantaged by their experiences’ (Bertolote and McGorry 2005). Finding ways to challenge internalised stigma could have important benefits for people with psychosis, but there are relatively few studies evaluating interventions that specifically target internalised stigma (Wiecznski 2000; Link, Stuenning et al. 2002). Existing research regarding the reduction of internalised stigma in

people with serious mental health problems such as psychosis have utilised group-based interventions to date. These studies have shown some promise regarding the use of cognitive therapy (CT) and/or psychoeducational approaches to reducing internalised stigma, as well as improving self-esteem, recovery and empowerment (Knight, Wykes et al. 2006; MacInnes and Lewis 2008; Lucksted, Drapalski et al. 2011). However, most have been small-scale studies, with serious methodological limitations including no use of randomisation, blinding or independent assessment, and often lacking a control condition. Recently, there have been two randomised controlled trials (RCTs) of group interventions incorporating CT techniques. One study in Hong Kong randomised 66 people with a diagnosis of schizophrenia to a 12 session CT-based stigma reduction programme in a group format, or a newspaper reading group. They found benefits in self-esteem post-treatment, but these were not maintained at follow-up (Tsang 2014). An RCT in the USA compared a narrative enhancement / CT approach to reducing internalised stigma to treatment as usual (TAU) in 39 people with severe mental health problems (mostly schizophrenia spectrum disorders). They found that the treatment was acceptable and feasible but no differences in outcome were observed (Yanos, Roe et al. 2012). A recent meta-analysis of RCTs of effectiveness of programs for reducing the stigma associated with mental health problems in general (rather than specific to psychosis) found that the pooled effect size across three studies, including the 2 preceding trials, was not statistically significant (Griffiths, Carron-Arthur et al. 2014).

CT for most mental health problems would hope to reduce internalised stigma as a result of processes such as normalisation, development of an idiosyncratic case formulation and the evaluation of negative beliefs about self, even if the primary outcome or treatment target was not self-stigma. There is some evidence for this in people with psychotic experiences, since a secondary analysis of the EDIE-2 trial, in which participants at high risk of developing psychosis (but not yet meeting criteria for a diagnosis of a psychotic disorder)

received a CT intervention (compared to TAU), demonstrated that internalised stereotypes about psychotic experiences were significantly reduced in the intervention group (Morrison, Birchwood et al. 2013). However, no study has examined the efficacy of individual CT for internalised stigma in people meeting criteria for psychotic disorders, and it is possible that an intervention where the primary focus is the reduction of internalised stigma may be better suited to this purpose. Therefore, the aim of this pilot trial was to evaluate the feasibility and acceptability of an individualised CT intervention for internalised stigma in people with psychosis, and to generate data that will facilitate the calculation of power for a definitive trial. Hypotheses included that CT would be acceptable and would reduce the severity of internalised stigma and promote recovery and self-esteem in people with psychosis, in comparison to TAU at both end of treatment and follow up. This study followed guidance outlined by the MRC (Medical Research Council 2000) for complex interventions (representing a phase II/pilot study), in order to examine identification of appropriate outcome measures, estimates of recruitment and attrition, acceptability and feasibility of the intervention and a preliminary analysis of treatment effects.

2. Methods

2.1 Study design

We conducted a single-blind, pilot RCT between May 2013 and September 2014 at a centre in the North West of England. The study protocol was approved by the National Research Ethics Service of the UK's National Health Service (reference 10/H1011/61).

2.2 Participants

Trial entry criteria were that participants were in contact with mental health services, and either met ICD-10 criteria for schizophrenia, schizoaffective disorder or delusional

disorder or met entry criteria for an Early Intervention for Psychosis service (operationally defined using PANSS) in order to allow for diagnostic uncertainty in early phases of psychosis and the fact that most early episode cases within the UK will receive their services from such specialist teams, consistent with NICE guidelines (2014). Participants also had to score >60 on the Internalised Stigma of Mental Illness Scale-Revised (ISMI-R), as indicative of at least moderate difficulties associated with internalised stigma; this cut-off was chosen on the basis of both distribution of scores from a large sample of service user participants (Ritsher, Otilingam et al. 2003) and face validity in terms of item response. Participants were identified via care coordinators and relevant mental health staff within participating mental health trusts. Ten participants (34%) had a diagnosis of a schizophrenia spectrum disorder, four (14%) had a diagnosis of bipolar disorder with psychotic features, one (3%) was diagnosed with schizoaffective disorder, and the remaining 14 (47%) were had experienced a first episode of psychosis and were receiving care from an early intervention for psychosis team. Eleven participants were referred from Community Mental Health Teams, 16 from Early Intervention Services, and one each from Assertive Outreach and Criminal Justice Liaison. Exclusion criteria were: moderate to severe learning disability; organic impairment; participants not having the capacity to consent to research participation; non-English speaking participants (since this would prevent the use of standardised assessment instruments); acute inpatient settings; primary diagnosis of a drug or alcohol dependency; and concurrent psychological therapy. All participants provided written informed consent.

2.3 Randomisation and masking

Participants were randomly assigned electronically (1:1) by an administrator using the computerised system Sealed Envelope (<https://www.sealedenvelope.com>) with permuted blocks of four, six and eight, to receive CT plus TAU and monitoring, or to TAU plus

monitoring. Email notifications of the allocation were sent to trial therapists and the trial's principal investigator. The trial assessor was independent of the randomisation process and blind to group allocation in order to facilitate unbiased rating of a semi-structured interview measure of stigma (SIMS: a measure developed specifically for this study) at the baseline, 4 and 7 month follow-ups. Several procedures were used to protect the blind: therapists had separate office space from the trial assessor; therapists and the trial assessor were required to consider diary arrangements in view of potential blind breaks; and participants were reminded not to talk about treatment allocation with the trial assessor. Two blind breaks occurred (7% of the sample), both involving participants in TAU and were reported using a standard form.

2.4 Sample Size

We chose a recruitment target of 30 in order to be able to evaluate feasibility of recruitment and retention and suitability of outcome measures. The proposed sample size is adequate to obtain reliable sample size estimates (Browne 1995), and facilitate the main aims of a pilot trial, including feasibility of trial procedures and a production of a realistic power calculation for a future definitive study. Power calculations are not recommended for a feasibility trial (Lancaster, Dodd et al. 2004).

2.5 Measures

The primary outcome was total score on the ISMI-R which was assessed at baseline, 4 months and 7 months, since this was also used for entry criteria. The ISMI-R is a 29-item questionnaire assessing internalised stigma covering four subscales: 'alienation'; 'stereotype endorsement'; 'perceived discrimination'; and 'social withdrawal'. Items are scored on a 4-point Likert scale, from strongly disagree to strongly agree. Total scores were calculated by summing the items. This measure was revised by the research team such that the term 'mental

illness' in its original form was replaced with 'mental health problems'. This was in response to consultation with a service user reference group during the study design stage, who advised that many service users reject the idea of being 'mentally ill' and that such terminology may in-itself be stigmatising for participants. Since the wording was changed, the internal consistency of the revised scale was examined with our sample using the baseline data; it was found to have good reliability ($\alpha = 0.86$).

Secondary outcomes included the Semi-Structured Interview Measure of Stigma (SIMS), a clinician-administered, 11-item semi-structured interview based on three categories of stigma identified in the literature: 'perceived stigma'; 'experienced stigma'; and 'internalised stigma'. Items are scored between 0 (not present) to 4 (severe). This interview schedule was developed specifically for this trial, and is currently being validated; however, within this sample we examined the psychometric properties and found good internal reliability ($\alpha = 0.84$) and good convergent validity (the Pearson's correlation with the ISMI-R was $r = 0.66$, $p < 0.001$). A shortened 16-item version of the Stigma Scale (KSS; (King, Dinos et al. 2007)) was used as a further measure of stigma. Items are scored on a 5-point Likert scale, from strongly disagree to strongly agree. This shortened version included the subscales of 'disclosure' and 'positive aspects', but not the 'discrimination' subscale which is less likely to capture change over time. The Process of Recovery Questionnaire – Short form (QPR (Law, Neil et al. 2014)) was used to measure user-defined recovery. This is a 15-item questionnaire which was developed collaboratively with service users and which measures subjective recovery. Items are scored on a 5-point Likert scale, from disagree strongly to agree strongly. The Beck Depression Inventory for Primary Care (BDI-7; (Winter, Steer et al. 1999)) was used to measure depression. It is a 7-item scale and a score of greater than 3 indicates a probable diagnosis of major depressive disorder. The Beck Hopelessness Scale (BHS; (Beck, Weissman et al. 1974)) was used to measure hopelessness. It consists of

20 true/false items covering three factors: ‘feelings about the future’, ‘loss of motivation’; and ‘future expectations’. The Social Interaction Anxiety Scale (SIAS; (Mattick and Clarke 1998)) was used to measure social anxiety. It is a 20-item questionnaire with responses scored on a 5-point Likert scale from ‘not at all characteristic or true of me’ to ‘extremely characteristic or true of me’ with scores of 36 and over indicating a probable diagnosis of social anxiety disorder. Self-esteem was measured using the Self-Esteem Rating Scale – Short form (SERS-S; (Lecomte, Corbiere et al. 2006)), a 20-item questionnaire with responses scored on a 7-point Likert scale from never to always with higher scores indicating higher self-esteem. Finally, internalised shame was measured using the Internalised Shame Scale (ISS; (Cook 1987)), a 30-item questionnaire with responses scored on a 5-point Likert scale from never to almost always. We did not include a measure of psychotic symptoms on the basis of feedback from our service user reference group, who felt that a focus on such symptoms in the assessment process but not the treatment process would be confusing for participants and provide an inconsistent message.

2.6 Procedures

All participants received their routine treatment plus monitoring, which provided benefits over routine care because it aimed to provide warm, empathic, and non-judgemental face-to-face contact, supportive listening, and signposting to appropriate local services for unmet needs. Most assessments and therapy sessions took place in participants’ homes.

2.7 Intervention

In addition to routine treatment, participants allocated to the therapy condition received the individual CT intervention. This comprised a maximum of twelve hourly sessions over a 4 month period, and was based on a specific cognitive model of psychosis (Morrison 2001), with supplementary disorder specific models being used if appropriate (e.g.

Clark and Wells model of social anxiety (Clark and Wells 1995)). The assessment phase collaboratively explored the participants' experiences of psychosis and stigma, and identified a stigma-related problem list and goal (this took several sessions for some participants). The intervention included a number of CT techniques, but these were focused on working towards the stigma-related goals: guided discovery, skills development, normalising and belief change strategies, including behavioural experiments targeting stigma-relevant appraisals and evaluation of negative beliefs about self, including public stereotypes of psychosis. In addition, time was allocated to allow for exploration of the meaning of participants' diagnoses, validation of experiences of stigma and discrimination, and consideration of pros and cons of different ways of responding to stigma and discrimination. Therapy was enhanced by the use of published normalising guided self-help manuals, which include chapters such as 'Are my experiences abnormal?', 'What is normal?' and 'Feeling good about yourself' (Morrison, Renton et al. 2008). Four therapists contributed to the delivery of cognitive therapy. The number of participants treated by each therapist ranged from 1 to 6 (Mean=2.8, SD=2.4). Three therapists were clinical psychologists (doctoral level) and one was a trainee clinical psychologist. All therapists received additional training associated with the trial protocol as outlined above and regular clinical supervision. Fidelity was not examined formally due to lack of funding; however, we would expect fidelity to be reasonable, since trial specific supervision of all therapists was provided by the first author.

All participants received treatment as usual plus the three assessment sessions (incorporating an interview focused on experiences of stigma and discrimination from a research assistant), which represents an enhancement over routine care since it aimed to provide warm, empathic and non-judgemental face-to-face contact, supportive listening, signposting to appropriate local services for unmet needs and crisis management when required (usually by referral to a local crisis team, early intervention service or psychiatric

liaison within emergency departments). Treatment as usual was variable, with care mostly being received from Community Mental Health Teams (CMHTs) or early intervention services (EIS). In practice, those within EIS (5 in CT, 33.3% vs 11 in TAU, 78.6%) received regular care-coordination and psychosocial interventions including the offer of family interventions and the potential to receive CT, whereas those from other community based services (10 in CT, 66.7% vs 3 in TAU, 21.4%) often received little other than irregular contact with care coordinators.

2.8 Statistical analysis

Analyses were undertaken in SPSS (version 20) after completion of endpoint assessments; primary analysis was by intention-to-treat. Changes in all outcomes were analysed using ANCOVA with summed scores as dependent variables and the baseline value of the relevant outcome measure as a covariate. We analysed end of treatment and follow-up separately in order to utilise all available data, on the assumption that data were Missing at Random (Little and Rubin 2002).

3. Results

INSERT FIGURE 1, CONSORT DIAGRAM

INSERT TABLE 1, DESCRIPTIVES TABLE AT BASELINE by group

INSERT TABLE 2: MEANS, SDs, F, p values at 4 MONTHS AND 7 MONTHS

Figure 1 shows the trial profile. In terms of feasibility of the trial, it is clear from Figure 1 that recruitment was relatively successful, with a final sample that was 97% of the initial target. In total, 29 individuals were randomised, with 15 allocated to CT plus monitoring and 14 allocated to TAU plus monitoring. The referral to randomisation ratio was

2:1 and no participants declined participation after having being assessed as eligible, suggesting good willingness to be randomised and to consider CT for internalised stigma in psychosis. Baseline characteristics were similar between groups (Table 1), and a two-tailed t-test revealed no significant difference between groups on the primary outcome measure; however, age and proportion within EIS appeared different (with TAU being younger and more likely to be recruited from EIS). Retention within the trial was good with just one withdrawal in the TAU group (Figure 1), and missing data rates of 10.3% at 4 months and 6.9% at 7 months.

Engagement with CT was reasonable. Four participants randomised to therapy did not attend any sessions: two reported having changed their minds post-randomisation; one was unwilling to travel to a service location and could not be seen at home due to risk issues; one participant did not receive their allocation letter and an administrative error led to this not being followed up. Of those participants who did attend therapy, 9 (82%) had at least 6 or more sessions (which is a threshold we have used in previous trials to constitute a reasonable ‘dose’), with an average of 9.8 (SD=3.3, Range 3-13). Participants were interviewed about their experiences of stigma-focused CT, but the detailed results of these qualitative analyses are reported elsewhere (Wood, Burke et al. 2016); briefly, CT was found to be valuable by the majority of participants and psychoeducation, normalisation and feeling understood were identified as the most important elements.

Table 2 shows the results of the primary and secondary outcomes at end of treatment and follow-up (means and SDs, F statistics, alpha values and effect sizes (Cohen’s d)). Starting with the primary outcome (ISMI-R total scores), it can be seen that there is no significant difference between CT and TAU at either end of treatment or follow-up; however, visual examination would suggest a small, non-significant benefit of CT, and the difference

in standard deviations of the two groups is likely to cause statistical problems. Looking at the secondary outcomes, the estimated effects for all secondary outcomes are favouring CT, but not all are statistically significant. At end of treatment, we found a significant effect in favour of CT for internalised shame (ISS), depression (BDI-7), hopelessness (BHS) and self-rated recovery (QPR). However, it did not significantly improve internalised stigma (SIMS and KSS), social anxiety (SIAS) or self-esteem (SERS) at end of treatment, and none of the differences remained significant at follow-up. The majority of the observed effect sizes are in the moderate range (0.5-0.8).

Three potential serious adverse events were recorded during the trial; one was in a participant in the CT condition (a voluntary hospital admission which happened during the course of therapy) and two were participants in TAU (one attempted overdose followed by a voluntary hospital admission and one other voluntary hospital admission). These potential adverse events and hospital admissions were in separate participants, and none were considered related to trial participation.

4. Discussion

To our knowledge, this is the first RCT of individual CT for people with psychosis who have been selected on the basis of high levels of internalised stigma. Our trial has shown that CT is an acceptable intervention for people with psychosis experiencing high levels of internalised stigma, with relatively low drop-out/withdrawal rates and the majority of those allocated to CT receiving at least 6 sessions. We also demonstrated that CT for this population does significantly reduce the severity of several relevant variables in this population, although there was no statistically significant difference on our primary outcome measure. CT significantly improved levels of internalised shame, depression, hopelessness, and self-rated recovery. It did not improve internalised stigma, social anxiety or self-esteem,

although all the observed changes were in the desired direction but did not reach statistical significance. These results are consistent with findings from the clinical trials of group CT for internalised stigma to date; most trials have shown some promise, often on indirect measures such as self-esteem, depression and hopelessness, but have been underpowered to detect small to moderate effect sizes. The fact that we observed changes in internalised shame and a favourable trend for an interview-based measure of dimensions of internalised stigma suggests that individual CT may be capable of achieving more specific effects, and the examination of the effect sizes are also encouraging, although caution should be exercised in interpreting these since underpowered pilot trials are prone to findings that are not replicated in future definitive studies. There are a number of possible explanations for the lack of a between group effect on our primary outcome, other than lack of statistical power or an absence of an effect of treatment. It is possible that the change in wording resulting from service user input, in order to make the items less stigmatising, may have reduced the sensitivity or validity of the measure; similarly, the lack of a specified time frame in this measure may have been problematic. However, it is evident that there was a significant reduction at end of treatment in both groups (approximately 11 points in each group, on a measure with a standard deviation of 11 at baseline), which was sustained at follow-up. This suggests that both groups significantly reduced in internalised stigma over the trial; one possibility is that this is due to the differences in community teams that were providing routine care to the participants (with 78% in TAU vs 33% in CT receiving care from EIS, in which a core aspect of service philosophy is to reduce stigma and routine access to CT is more likely), while another possibility is that there are therapeutic benefits associated with the conversations that are facilitated by the SIMS interview that encourages discussion and reflection on experiences of stigma and discrimination, and the cognitive, behavioural and emotional dimensions of such experiences. Future trials in this area should consider

stratification of randomisation or standardisation of entry criteria by type of community team or service philosophy and document TAU received for individual participants and further research should explore potential benefits of semi-structured interviews such as the SIMS.

Our trial demonstrates methodological rigour in several ways, including a combination of self-report and interview measures, blinding of assessments, concealment of allocation and independent randomisation. However, there are also several methodological difficulties with our trial. We did not correct for multiple comparisons (for example, using Bonferroni's correction); however, we only had one primary outcome, and given that this was a pilot study, it would seem overly conservative to apply a more stringent alpha for secondary outcomes. The lack of an active control group that included non-specific factors such as contact time, warmth and empathy, also means that we are unable to exclude the possibility that the observed effects were due to such non-specific factors. The trial was not registered with a trial registry since it was an unfunded feasibility study with no intention to produce definitive results. However, this is still a limitation. The lack of funding also resulted in stretched resources, which contributed to the failure to engage 2 participants (due to an administrative error and a risk/setting-related difficulty). We had several measures of internalised stigma, which did not demonstrate a clear consistency in terms of sensitivity to change. Our interview measure, which was developed due to perceived limitations in the existing measures (including use of some items assessing lifetime prevalence, which are very unlikely to change in a short-term clinical trial), appeared most sensitive to detecting a possible treatment effect (showing a strong trend in favour of CT). The lack of a measure of psychotic experiences, while based on service user input to the trial design, does mean it was not possible to describe our sample in these terms or to examine relationships between internalised stigma and such experiences. Future trials in this area should give careful consideration to appropriate outcome measures that are sensitive to change. The exclusion of

people who were in inpatient settings also limits generalisability to those with acute episodes requiring admission to hospital, who are a population likely to be troubled by internalised stigma. Perhaps most importantly, our trial had very low statistical power with a small sample size; therefore, an adequately powered definitive randomised controlled trial is required.

There are several clinical implications arising from this study, although they need to be considered very cautiously, given the limitations of an underpowered pilot study. It would seem that targeting internalised stigma in people with psychosis who report high levels of stigma is feasible and acceptable. There is some encouragement that a relatively short-term intervention that focuses on internalised stigma can result in changes in internalised shame, self-rated recovery, depression and hopelessness. It is important to assess internalised stigma in people with psychosis, and CT may be an appropriate approach to address this if the person prioritises it as problematic and an appropriate shared stigma-relevant goal can be established. It is also encouraging that both groups reduced in internalised stigma, and it is possible that other factors, such as normalising interactions with mental health professionals in EIS, open discussions about stigma facilitated by the SIMS and an expansion of social networks resulting from CT and EIS may be helpful in reducing self-stigma. However, further research is required.

Acknowledgements

We recognize that the terms and language used in this paper are not universally endorsed. Where differences of opinion arose, the research team decided to use the term that was endorsed by the majority, whilst also respecting the views of others. We wish to thank the people who participated in this study and the Psychosis Research Unit Service User Reference Group (PRU-SURG) for their consultation.

References

- Angermeyer, M. C. and Matschinger, H.,2003. "Public beliefs about schizophrenia and depression: similarities and differences." *Soc Psychiatry Psychiatr Epidemiol* 38(9): 526-534.
- Angermeyer, M. C. and Matschinger, H.,2003. "The stigma of mental illness: effects of labelling on public attitudes towards people with mental disorder." *Acta Psychiatrica Scandinavica* 108: 304-309.
- Beck, A., Weissman, A., Lester, D. and Trexler, L.,1974. "The measurement of pessimism: The Hopelessness Scale." *Journal of Consulting and Clinical Psychology* 42: 861-865.
- Bertolote, J. and McGorry, P.,2005. "Early intervention and recovery for young people with early psychosis: consensus statement." *Br J Psychiatry* 187(48): s116-119.
- Birchwood, M., Mason, R., MacMillan, F. and Healy, J.,1993. "Depression, demoralization and control over psychotic illness: a comparison of depressed and non-depressed patients with a chronic psychosis." *Psychological Medicine* 23: 387-395.
- Birchwood, M., Trower, P., Brunet, K., Gilbert, P., Iqbal, Z. and Jackson, C.,2007. "Social anxiety and the shame of psychosis: a study in first episode psychosis." *Behaviour Research and Therapy* 45: 1025-1037.
- Brohan, E., Elgie, R., Sartorius, N. and Thornicroft, G.,2010. "Self-stigma, empowerment and perceived discrimination among people with schizophrenia in 14 European countries: The GAMIAN-Europe study." *Schizophrenia Research* 122(1-3): 232-238.
- Browne, R. H.,1995. "On the use of a pilot sample for sample size determination." *Statistics in Medicine* 14(17): 1933-1940.
- Clark, D. M. and Wells, A.,1995. A cognitive model of social phobia. *Social phobia: Diagnosis, assessment, and treatment*. R. G. Heimberg and M. R. Liebowitz. New York, NY, US, Guilford Press: 69-93.
- Cook, D. R.,1987. "Measuring shame: The Internalized Shame Scale." *Alcoholism Treatment Quarterly* 4(2): 197-215.
- Corrigan, P., Kerr, A. and Knudsen, L.,2005. "The stigma of mental illness: Explanatory models and methods for change." *Applied and Preventive Psychology* 11: 179-190.
- Corrigan, P. W. and Watson, A. C.,2002. "The paradox of self-stigma and mental illness." *Clinical Psychology: Science and Practice* 9: 35 - 53.
- Corrigan, P. W. and Watson, A. C.,2007. "The stigma of psychiatric disorders and gender, ethnicity, and education of the perceiver." *Community Mental Health Journal* 43(5): 439-458.

- Crisp, A. H., Gelder, M. G., Goddard, E. and Meltzer, H.,2005. "Stigmatization of people with mental illnesses: a follow-up study within the Changing Minds Campaign of the Royal College of Psychiatrists." *World Psychiatry* 4(2): 106 - 113.
- Crisp, A. H., Gelder, M. G., Rix, S., Meltzer, H. I. and Rowlands, O. J.,2000. "Stigmatisation of people with mental illness." *British Journal of Psychiatry* 177: 4 - 7.
- Eagles, J. M., Carson, D. P., Begg, A. and Naji, S. A.,2003. "Suicide prevention: a study of patients views." *British Journal of Psychiatry* 182: 261-265.
- Finzen, A.,1996. *Der Verwaltungsrat ist schizophren. Die Krankheit und das Stigma*. Bonn, Psychiatrie-Verlag.
- Goffman, E.,1963. *Stigma: notes on the management of spoiled identity*, Harmondsworth, Middlesex: Penguin Books.
- Griffiths, K. M., Carron-Arthur, B., Parsons, A. and Reid, R.,2014. "Effectiveness of programs for reducing the stigma associated with mental disorders. A meta-analysis of randomised controlled trials." *World Psychiatry* 13: 161-175.
- King, M., Dinos, S., Shaw, J., Watson, R., Stevens, S. and Pasetti, F.,2007. "The Stigma Scale: development of a standardised measure of the stigma of mental illness." *British Journal of Psychiatry* 190: 248 - 254.
- Knight, M. T. D., Wykes, T. and Hayward, P.,2006. "Group treatment of perceived stigma and self-esteem in schizophrenia: a waiting list trial of efficacy." *Behavioural and Cognitive Psychotherapy* 34: 305 - 318.
- Lancaster, G. A., Dodd, S. and Williamson, P. R.,2004. "Design and analysis of pilot studies: recommendations for good practice." *Journal of Evaluation in Clinical Practice* 10(2): 307-312.
- Law, H., Neil, S. T., Dunn, G. and Morrison, A. P.,2014. "Psychometric properties of the Questionnaire about the Process of Recovery (QPR)." *Schizophrenia Research* 156(2): 184-189.
- Lecomte, T., Corbiere, M. and Laisne, F.,2006. "Investigating self-esteem in individuals with schizophrenia: Relevance of the Self-Esteem Rating Scale-Short Form." *Psychiatry Research* 143: 99-108.
- Lincoln, T. M., Arens, E., Berger, C. and Rief, W.,2008. "Can Antistigma Campaigns Be Improved? A Test of the Impact of Biogenetic Vs Psychosocial Causal Explanations on Implicit and Explicit Attitudes to Schizophrenia." *Schizophr Bull* 34(5): 984-994.
- Link, B. and Phelan, J. C.,2001. "Conceptualizing stigma." *Annual Review of Sociology* 27: 363-385.

- Link, B. G., Struening, E. L., Neese-Todd, S., Asmussen, S. and Phelan, J. C.,2001. "Stigma as a barrier to recovery: the consequences of stigma for the self-esteem of people with mental illness." *Psychiatric Services* 52: 1621 - 1626.
- Link, B. G., Struening, E. L., Rahav, M., Phelan, J. C. and Nuttbrock, L.,1997. "On stigma and its consequences: evidence from a longitudinal study of men with dual diagnosis of mental illness and substance abuse." *Journal of Health and Social Behavior* 38: 177 - 190.
- Link, B. G., Stuenkel, E. L., Neese-Todd, S., Asmussen, S. and Phelan, J.,2002. "On describing and seeking to change the experience of stigma." *Psychiatric Rehabilitation Skills* 6: 201-231.
- Little, R. J. A. and Rubin, D. B.,2002. *Statistical Analysis with Missing Data*. London, John Wiley and Sons.
- Livingston, J. D. and Boyd, J. E.,2010. "Correlates and consequences of internalized stigma for people living with mental illness: A systematic review and meta-analysis." *Social Science & Medicine* 71(12): 2150-2161.
- Lucksted, A., Drapalski, A., Calmes, C., Forbes, C., DeForge, B. and Boyd, J.,2011. "Ending Self-Stigma: Pilot Evaluation of a New Intervention to Reduce Internalized Stigma Among People with Mental Illnesses." *Psychiatric Rehabilitation Journal* 35: 51-54.
- MacInnes, D. L. and Lewis, M.,2008. "The evaluation of a short group programme to reduce self-stigma in people with serious and enduring mental health problems." *Journal of Psychiatric & Mental Health Nursing* 15: 59 - 65.
- Mattick, R. P. and Clarke, J. C.,1998. "Development and validation of measures of social phobia scrutiny fear and social interaction anxiety." *Behavior Research and Therapy* 36: 455-470.
- Medical Research Council,2000. *A Framework for development and evaluation of RCTs for Complex Interventions to Improve Health*. London, Medical Research Council.
- Morrison, A., Renton, J., French, P. and Bentall, R.,2008. "Think you're crazy? Think again: a resource book for cognitive therapy for psychosis."
- Morrison, A. P.,2001. "The interpretation of intrusions in psychosis: An integrative cognitive approach to hallucinations and delusions." *Behavioural and Cognitive Psychotherapy* 29: 257-276.
- Morrison, A. P., Birchwood, M., Pyle, M., Flach, C., Stewart, S. L. K., Byrne, R., Patterson, P., Jones, P. B., Fowler, D., Gumley, A. I. and French, P.,2013. "Impact of cognitive therapy on internalised stigma in people with at-risk mental states." *The British Journal of Psychiatry* 203(2): 140-145.
- National Institute for Health and Care Excellence,2014. *Psychosis and schizophrenia in adults: treatment and management*. UK, NICE.

- Ritsher, J. B., Otilingam, P. G. and Grajales, M.,2003. "Internalized stigma of mental illness: psychometric properties of a new measure." *Psychiatry Research* 121: 31 - 49.
- Ritsher, J. B. and Phelan, J. C.,2004. "Internalized stigma predicts erosion of morale among psychiatric outpatients." *Psychiatry Research* 129: 257 - 265.
- Thornicroft, G.,2007. "Most people with mental illness are not treated." *Lancet* 370: 807-808.
- Thornicroft, G., Brohan, E., Rose, D., Sartorius, N. and Leese, M.,2009. "Global pattern of experienced and anticipated discrimination against people with schizophrenia: a cross-sectional survey." *Lancet* 373: 408-415.
- Thornicroft, G., Rose, D. and Kassam, A.,2007. "Discrimination in health care against people with mental illness." *International Review of Psychiatry* 19(2): 113-122.
- Tsang, H. W. H.,2014. "Stages of change, self-stigma, and treatment compliance among Chinese adults with severe mental illness." *Hong Kong Medical Journal* 19(6): 54-58.
- Wiecznski, D. M.,2000. "Effects of a stigma management group for individuals with mental illnesses." *Dissertation Abstracts International: Section B: the Sciences and Engineering* 61(2786).
- Winter, L. B., Steer, R., Jones-Hicks, L. and Beck, A. T.,1999. "Screening for major depressive disorder in adolescent medical outpatients with the Beck Depression Inventory for Primary Care." *Journal of Adolescent Health* 24: 389-394.
- Wood, L., Birtel, M., Alsawy, S., Pyle, M. and Morrison, A.,2014. "Public perceptions of stigma towards people with schizophrenia, depression and anxiety." *Psychiatry Research*.
- Wood, L., Burke, E., Byrne, R. and Morrison, A.,2016. "Examining service user experiences of a Cognitive Therapy intervention for self-stigma in psychosis." *Psychosis: Psychological, social and integrative approaches*(in press).
- Yanos, P. T., Roe, D. and Lysaker, P. H.,2012. "Narrative Enhancement and Cognitive Therapy: A new group-based treatment for internalised stigma among persons with severe mental illness." *International Journal of Group Psychotherapy* 61(4): 576.

TABLE 1: Baseline characteristics of the sample

	Whole sample (N=29)	CBT (N =15)	TAU (N =14)
	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	34.34 (13.26)	39.00 (13.50)	29.36 (10.02)
Male: Female ratio	23:6	12:3	11:3
ISMI-R	80.34 (11.06)	78.27 (9.40)	82.57 (12.57)
SIMS	24.52 (6.64)	23.80 (7.37)	25.29 (5.93)
KSS	41.93 (9.84)	40.07 (11.87)	43.79 (7.27)
QPR	27.056(11.76)	27.50 (9.12)	26.31 (14.43)
BDI-7	10.04 (5.41)	10.50 (4.16)	9.57 (6.56)
BHS	12.97 (6.30)	13.57 (5.52)	12.37 (7.16)
SIAS	50.22 (16.14)	48.94 (16.56)	51.50 (16.22)
ISS	77.85 (23.27)	76.26 (24.01)	79.43 (23.30)
SERS	65.43 (24.07)	66.43 (24.01)	64.43 (25.00)

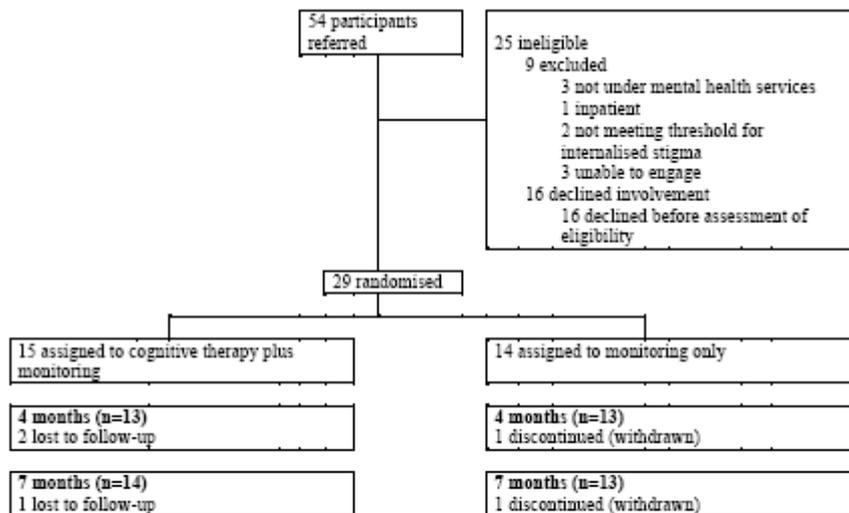
TABLE 2: Descriptive statistics, ANCOVA results and effect sizes (Cohen's d) at 4 and 7 months

Variable	End of treatment (4 months)		Follow-up (7 months)		End of treatment			Follow-up		
	Mean (SD)		Mean (SD)		F	p	d	F	p	d
	CBT	TAU	CBT	TAU						
ISMI-R*	67.29 (10.09)	71.20 (16.34)	66.62 (9.71)	69.26 (18.38)	0.052	0.822	0.09	0.046	0.832	0.09
SIMS	17.45 (7.47)	22.81 (7.96)	15.35 (7.98)	19.01 (7.77)	2.97	0.099	0.65	1.50	0.236	0.41
KSS	34.75 (8.82)	40.32 (6.57)	32.76 (9.73)	38.69 (7.33)	2.27	0.146	0.49	1.98	0.173	0.50
QPR	38.71 (7.55)	25.75 (14.59)	39.17 (11.22)	31.58 (14.41)	12.84	0.002	1.10	3.34	0.082	0.67
BDI-7	6.33 (4.21)	9.15 (5.21)	6.83 (4.57)	6.92 (5.24)	4.39	0.048	0.59	.376	0.546	0.16
BHS	7.12 (5.23)	10.77 (6.31)	9.42 (6.57)	10.25 (7.31)	7.73	0.011	0.72	1.81	0.191	0.38
SIAS	39.58 (19.32)	48.77 (17.82)	37.00 (19.26)	46.91 (17.83)	1.95	0.177	0.51	3.19	0.088	0.68
ISS	61.18 (18.36)	74.00 (22.51)	60.00 (29.13)	67.31 (24.53)	4.84	0.039	0.56	.796	0.382	0.34
SERS	79.00	70.62	83.58	73.15	1.70	0.206	0.34	2.87	0.104	0.55

	(23.03)	(25.06)	(29.84)	(24.96)						
--	---------	---------	---------	---------	--	--	--	--	--	--

NB * ISMI-R was the primary outcome

Figure 1: Participant flow



Highlights

- Stigma-focused CT is feasible and acceptable in people experiencing psychosis who have internalised stigma
- CT showed promise for reducing internalised shame and hopelessness and improving self-rated recovery
- A definitive, appropriately powered trial is required and appears both feasible and deliverable

Accepted manuscript