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Exploring the development, validity and utility of the Short Form version of the CHoice of Outcome In Cbt for psychosEs (CHOICE-SF): A patient reported outcome measure of psychological recovery.

Rebecca Webb¹, Gergely Bartl¹, Bryony James¹, Rosie Skan¹, Emmanuelle Peters^{3,4}, Anna-Marie Jones², Philippa Garety^{3,5}, Elizabeth Kuipers^{3,4,5}, Mark Hayward¹⁻² Kathryn Greenwood^{1-2*}

Affiliations

1. School of Psychology, University of Sussex, BN1 9RH
2. R&D Department, Sussex Partnership NHS Foundation Trust, BN3 7HZ.
3. Institute of Psychiatry, Psychology and Neuroscience, King's College London, Department of Psychology, SE5 8AF.
4. Psychological Interventions Clinic for outpatients with Psychosis (PICuP), South London and Maudsley (SLaM) NHS Foundation Trust, Denmark Hill, London SE5 8NZ
5. National Institute for Health Research (NIHR) Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London

Corresponding Author:

Professor Kathryn Greenwood, School of Psychology, Pevensey 1, University of Sussex, Falmer, Brighton. BN1 9RP. Telephone +44 1273 678409. Email k.e.greenwood@sussex.ac.uk

Abstract

The original CHOICE measure was designed in collaboration with experts by experience as a patient reported ‘Psychological Recovery’ outcome measure for Cognitive Behavioural Therapy for Psychosis (CBTp). A short version (CHOICE-SF) was developed to use as a brief outcome measure, with a focus on sensitivity to change, for use in future research and practice. CHOICE-SF was developed and validated using three separate samples, comprising 640 service users attending one of two transdiagnostic clinics for (i) CBT for psychosis or (ii) therapies for voice hearing or (iii) who took part in the treatment as usual arm of a trial. In the initial sub-sample of 69 participants, items from the original CHOICE measure with medium to large effect sizes for change pre to post CBTp were retained to form the CHOICE-SF. Internal consistency, construct validity and sensitivity to change were confirmed, and the factor structure was examined in 242 participants. Specificity was confirmed by comparison with 44 participants who completed CHOICE at two time points but did not receive therapy. Validation of CHOICE-SF was carried out by confirming factor structure and sensitivity to change in a new sample of 354, and a sub-sample of 51 participants, respectively. The CHOICE-SF comprised 11 items and 1 additional personal goal item. A single factor structure was confirmed, with high internal consistency, construct validity and sensitivity to change. The CHOICE-SF is a brief, psychometrically robust measure to assess change following psychological therapies in research and clinical practice for people with psychosis and severe mental illness.

Keywords: Psychosis, Patient Reported Outcome Measurement, Psychological therapy, Cognitive therapy.

Introduction

One of the key interventions for psychosis is Cognitive Behavioural Therapy¹. Previous research examining the effectiveness of cognitive behavioural therapy for psychosis (CBTp) has mainly focused on the reduction of psychosis symptoms, using clinician-rated scales². However, it has been argued that CBTp focuses on alternative outcomes that are not well captured by current measures³⁻⁴. Specifically, CBTp targets symptom related distress and the impact on functioning, associated unhelpful thinking biases, and psychological and emotional recovery, as opposed to symptom reduction⁵⁻⁶.

Furthermore, the goals of CBTp are agreed in collaboration with service users, who have reported that other issues, such as empowerment, choice, control, and personal fulfilment are of central concern⁷. CBTp, therefore, may address a variety of issues such as negative beliefs about psychosis, self-esteem, self-stigma, self-confidence and empowerment⁸⁻¹¹.

As a result of this mismatch between CBTp aims and available measures, a new outcome measure of CBTp was developed and was designed to reflect both the priorities of CBTp and those of the service user (CHoice of Outcome In Cbt for psychoses (CHOICE))¹². The initial measure was developed in collaboration with service user experts by experience, through qualitative analysis and Delphi consultation to reach consensus on the questionnaire items. The final measure was found to have one single factor, with good test-retest reliability, face and construct validity, and sensitivity to change¹². Whilst constituting a single factor, the measure included both generic recovery related items, such as ‘feeling happy’ and ‘a sense of being in control of my life’, and CBT specific cognitive and coping items such as ‘positive thinking’,

‘ways of dealing with unpleasant feelings and emotions’ and ‘ways of dealing with distressing experiences’. Since publication, the original CHOICE measure has been used in at least four randomised trials and three observational studies to assess the effectiveness of various psychological interventions including mindfulness, structured communication, relating therapy as well as group-based, self-help and one-to-one CBT in individuals with psychosis experiences¹³⁻¹⁹. It has been referenced in recent policy documents²⁰ and has been adopted by routine clinical services in at least 10 NHS trusts around the UK, as well as by UK clinical psychology training departments, and international services in Asia, America and Europe, where it has been translated into other languages²¹. It has been described as an important measure of ‘self- defined recovery that may be valued more highly than symptom reduction alone by many service users’⁴.

The original CHOICE questionnaire comprised 24 items, covering a range of issues, each rated on two separate sub-scales of severity and satisfaction. Participants first rated the severity of each item on a Likert scale from 0 (worst) to 10 (best), and then rated their level of satisfaction in relation to each item on a separate Likert scale from 0 (not at all satisfied) to 10 (very satisfied). However, the length of the original CHOICE measure was a potential drawback, as participants were required to make 48 individual ratings which may be a challenge for some people with psychosis where characteristic difficulties with concentration, motivation and cognition may hamper completion²²⁻²³. Furthermore, there was a specific need for a measure that could be used to measure change over short time frames, including on a session-by-session basis, as part of the Improving Access to Psychological Therapies in Severe Mental Illness (IAPT-SMI) programme. This study therefore aimed to develop a brief, psychometrically robust and clinically valuable

version of CHOICE that would also be highly sensitive to change over a short (one week) time frame. Initial development commenced, at the start of the IAPT-SMI programme in 2013, and validation has subsequently been conducted across several distinct phases in a large sample of participants receiving psychological therapies.

Methods

A total of 640 patients with psychosis experiences and Severe Mental Illness (in receipt of secondary care services) contributed data in one of two phases: (i) the initial development; or the (ii) the secondary validation of the CHOICE short form (CHOICE-SF).

Development phase

Participants.

The initial participants were 69 psychosis service users from the Psychological Interventions Clinic for outpatients with Psychosis (PICuP) run by the South London and Maudsley NHS Foundation Trust. They received CBTp according to NICE guidelines and provided full choice data at two time points: 1) an initial screening assessment (either prior to joining the waiting list (n=45) or immediately pre-therapy (n=24)); and 2) post CBTp. See Peters et al. for further details about assessment procedures and therapy in PICuP²⁴. A larger sample of 242 individuals with psychosis from PICuP, which included these 69 participants, completed the original full CHOICE measure on at least one of 5 time points (initial screening, immediately pre-therapy, mid-therapy, post-therapy or follow up) and provided data for the initial factor analysis.

Measures

Service users were asked to complete 5 measures as part of routine data collection by the clinic. All measures have good reliability and validity in a psychosis sample.

- (i) *The original CHOICE measure*¹² - a 24-item self-report questionnaire, which provides mean scores for severity and satisfaction with a range of aspects of psychological wellbeing, as well as additional self-reported items or therapy goals that are unique to the individual. Each item is reported on an 11 point scale from 0 (worst) to 10 (best). The mean score is used.
- (ii) *The Beck Depression Inventory (BDI)*²⁵ - a 21-item measure of depressive symptoms and cognitions, on which each item is rated on a 4-point scale from 0-3 to produce a total score, from 0-63, where higher scores reflect more severe symptoms.
- (iii) *The Beck Anxiety Inventory (BAI)*²⁶ - a 21-item measure of physiological anxiety symptoms, on which each item is rated on a 4-point scale from 0 (not at all) to 3 (severely) to produce a total score, from 0-63, where again high scores reflect more severe symptoms.
- (iv) *The Manchester Assessment of Quality of Life (MANSA)*²⁷ - a 16-item measure that assesses satisfaction with life across 12 subjective measures and 4 objective measures including areas such as employment, finances, leisure, friendships, relationships, personal safety, accommodation, and physical and mental health. Each item is rated on a 7-point scale from 1 (couldn't be worse) to 7 (couldn't be better). The total score was used.
- (v) *The Psychotic Symptoms Rating Scale (PSYRATS)*²⁸ – which comprises a 17 item, five point (0-4) scale, multidimensional measure. The delusion scale comprises 6 items that capture distress, disruption, preoccupation and conviction (scores range from 0-

24). The Hallucinations Scale has 11 items that include frequency, duration, loudness, location, intensity, distress, disruption, negative content and beliefs about origin (scores range from 0-44).

A comparison group of 44 participants with a diagnosis of schizophrenia, completed the full CHOICE at two time points 16 weeks apart, as part of the Treatment As Usual control arm of a randomized trial conducted separately by our group¹⁶.

Statistical Analysis

The severity and satisfaction scales of the original CHOICE measure are highly correlated. In the interests of developing a much briefer scale, only the CHOICE severity scale was selected, as it is a simpler construct than satisfaction which is impacted conceptually by knowledge of opportunities and expectancies, and methodologically by overlaps with health outcomes²⁹⁻³⁰. *Cohen's d* effect sizes were calculated to reflect the change on each of the individual items of the CHOICE measure, using the pre-CBTp standard deviation and mean difference pre-post therapy for the 69 participants who provided data pre- and post-CBTp. Items where the effect size was medium-large (Cohen's $d > 0.55$) were retained, whilst those with smaller effect sizes (.28-.54) were omitted. Using this same sample of 69 participants, internal consistency (Cronbach's alpha) and sensitivity to change (one-way ANOVA) were also calculated, and specificity was confirmed by comparison with the 44 participants who provided full CHOICE data at 2 time points, from which the short form was derived, but who did not receive therapy. Construct validity was assessed by correlating pre-therapy scores from the CHOICE-SF with the BDI, BAI, MANSA and PSYRATS. The reliable change index³¹⁻³³ and factor structure were also calculated in the

whole sample of 242 participants, the latter using principal axis factoring. The Kaiser-Meyer-Olkin (KMO) value was 0.91, and the Bartlett's Test of Sphericity reached significance, thus supporting the suitability of the data for factor analysis. Sample sizes were large, and greater than those reported for reliability and factor analysis in the original CHOICE paper. The single factor, high loading items, communalities in the 0.5 range, with > 20-30 participant per item provide sufficient power and a robust factor structure for both EFA and CFA analysis³⁴⁻³⁶. For the sensitivity analysis, a sample size calculation based on a medium pre-post effect size consistent with published literature (Cohen's $d=0.4$) using a 2-sided paired t-test at the 5% alpha level and 80% power, resulted in a minimum required sample size of $N=59$.

Secondary Validation Phase.

Participants

The factor structure of the CHOICE-SF was further examined using data provided by a further 354 transdiagnostic voice-hearing participants who attended an initial assessment at the Sussex Voices Clinic (a specialist outpatient service offered by Sussex Partnership NHS Foundation Trust) between May 2014 and June 2018, and completed the CHOICE-SF. Sensitivity to change of the CHOICE-SF was examined in 51 of these 354 participants who also completed the CHOICE-SF following at least 2- 4 sessions of Coping Strategy Enhancement for voices³⁷ delivered by therapists with a range of expertise, and either: 8-12 sessions of group person based cognitive therapy for distressing voices¹⁶, 6-16 sessions of individual relating and assertiveness therapy for voices¹⁸, or 6-8 sessions of individual Guided self-help cognitive behavioural Intervention for distressing Voices¹⁹, delivered by expert therapists.

Analysis

In the second validation phase, an a priori model of the questionnaire data was tested using Confirmatory Factor Analysis based on a sample of N=354 participants. The analysis was performed in the R software environment³⁸, using the lavaan package³⁹, and plots were created using lavaanPlot⁴⁰. Full Information Maximum Likelihood estimation was used in order to handle missing data points whilst improving bias and efficiency⁴¹. In addition to the Chi-Square test of exact fit, model fit was assessed using global and local fit indices: CFI (Comparative Fit Index)⁴², TLI (Tucker-Lewis Index)⁴³, GFI (Goodness of Fit Index), as well as RMSEA (root mean square error of approximation)⁴⁴ and SRMR (standardized root mean square residual)⁴⁵. The magnitude and significance of factor loadings of the resulting model was also evaluated.

Two paired t-tests were then conducted to test the measure's sensitivity to change between baseline and follow-up: the first using the mean score of the 11 CHOICE-SF items; and the second using the personal goal item alone. The personal goal item was analysed separately, as this item is personal to the individual and is not necessarily completed by all service users. Bayes factors were also calculated where possible, as they enable a distinction between results that refute a hypothesis and those that reflect insufficient evidence, from which no conclusions can be drawn⁴⁶⁻⁴⁷.

Results

Development phase

Participants

Characteristics of the participants who took part in the development of the CHOICE-SF can be found in Table 1.

[Insert Table 1 about here]

Development of the short form

Item selection

12 out of 24 items had medium-large effect sizes (Cohen's d ranging from 0.55-0.77) for change with CBTp in the full ($n = 69$), and even larger effect sizes (Cohen's d ranging from 0.64-0.98) in the smaller sub-sample ($n=24/69$) with immediate pre-post therapy data. One of these items: 'The ability to question the way I look at things' overlapped conceptually with another 'The ability to see things from another point of view', and internal consistency was found to be marginally greater (Cronbach's $\alpha = 0.93$) with the former item. Therefore, only the first was included, to provide a final CHOICE short form measure (see Supplementary materials for the final CHOICE-SF) comprising 11 items, and 1 blank item for recording a personal goal.

Internal consistency, construct validity and sensitivity to change

The final CHOICE-SF had high internal consistency [Cronbach's $\alpha = 0.93$], and was highly sensitive to change with CBTp [$df(68)$, $t = -6.08$, $p < .001$, ($CI_{95} = -2.19 - -1.10$)] with a large effect size for change [Cohen's $d = -0.84$; ($CI_{95} = -1.15 - -0.54$)]. The same sensitivity and effect size calculations for the original full CHOICE in the same 69 participants, yielded slightly lower effect size, [$df(68)$, $t = -5.56$, $p < .001$, ($CI_{95} = -1.98 - -0.93$); Cohen's $d = -0.73$; ($CI_{95} = -1.03 - -0.44$)]. In contrast, and in support of the specificity of change to the intervention, the comparison group who received no intervention, experienced no significant change on the

CHOICE-SF [df(43), $t = -1.09$, $p = 0.28$, ($CI_{(95)} = -1.09 - 0.20$); Cohen's $d = -0.15$; ($CI_{(95)} = -0.57 - 0.27$)]

Construct validity was good with the CHOICE-SF mean score correlating positively with the MANSA ($r = 0.70$ $p < .001$) and negatively with the BDI ($r = -0.70$ $p < .001$ $n = 68$) and BAI ($r = -0.52$ $p < .001$ $n = 68$). However, the CHOICE-SF did not correlate with the PSYRATS delusions ($r = -0.277$ $p = .069$ $n = 45$) or voices scales ($r = -0.313$ $p = .098$ $n = 30$). These findings are consistent with and stronger than those for the original CHOICE measure where the severity scale correlated significantly with the MANSA ($r = 0.52$), BDI ($r = -0.70$), BAI ($r = -0.48$), distress/disruption items on the PSYRATS ($r = -0.26 - 0.28$), but not with traditional PSYRATS symptom measures of conviction with delusions ($r = 0.11$), or frequency, location or beliefs about voices ($r = 0.01$ to 0.10)¹².

Initial Factor Analysis

Following item selection, internal consistency, validity and sensitivity analysis, a principal axis factoring analysis, was conducted on the larger sample of 242 participants. This revealed a single factor with an eigenvalue exceeding 1, which explained 52.3%, of the variance. The factor loadings are presented in Table 2.

[Insert Table 2 about here]

The reliable change index

The Reliable Change Index (RCI)³¹⁻³³ for CHOICE-SF was calculated for items 1-11 only (as the goal item is not used by all service users), using the standard deviation ($SD = 1.983$) from the full

242 participant sample. The RCI was found to be 1.45, indicating that a change in mean score of 1.45 points or more is considered a statistically reliable change. This compares to the RCI derived from the standard deviation (1.93) and reliability (0.83) of the original CHOICE questionnaire¹² of 2.2 points. With regards to the initial development sample (n=69), 82% of this sample demonstrated some improvement, i.e. an increase in total score, on the CHOICE-SF following CBTp and over half of participants (53%) showed a statistically reliable improvement, of at least 1.45 points on the CHOICE-SF.

Secondary validation of the short form.

Participants

Characteristics of participants who took part in the secondary validation can be found in Table 3.

[Insert Table 3 about here]

Secondary factor analyses

For the CFA model of a single ‘Psychological Recovery’ factor with 11 indicators, the Chi-Square test was significant, $\chi^2=175.408$, $df=44$, $p<.001$, as can occur in smaller datasets. Other fit indices suggested a good or acceptable level of approximate fit: CFI=0.942, TLI=0.942, GFI=0.953, RMSEA=0.092, CI₍₉₀₎ [0.076; 0.106] and SRMR=0.042. In order to evaluate potential errors of model specification, the standardised residuals matrix was evaluated as suggested by Kline⁴⁸. Two adjacent items (Q9: Understanding myself and my past and Q10: Understanding my experiences) were found to have a high ($>|.10|$) residual.

The CFA model allowing for correlated errors between Q9 and Q10 improved model fit resulting in a lower but significant Chi Square value, $\chi^2=92.124$, $df=43$, $p<.001$. Other indices also suggested an improved fit compared to the previous model, CFI=0.978, TLI=0.972, GFI=0.975. The root mean square error of approximation estimate was RMSEA=0.057, $CI_{(90)} [0.041; 0.073]$ allowing the rejection of the poor-fit hypothesis ($<.10$). The SRMR also decreased and was below the value of 0.08, SRMR = 0.029. All factor loading (ranging from 0.667 and 0.815) were significant indicators of Psychological Recovery, as displayed below in Table 4.

Secondary sensitivity to change

The t-tests assessing sensitivity to change again revealed a significant difference between baseline and post-therapy mean score for the CHOICE-SF (11 items) [$df(50)$, $t = 5.34$, $p<0.001$, ($CI_{(95)} = 2.04 - .92$), Bayes factor = 38614). A larger significant difference was found for the personal goal item [$df(53)$, $t = 7.93$, $p < 0.0001$, ($CI_{(95)} = 2.19 - 3.67$), Bayes factor = 846). Bayes factors were greater than 100, which demonstrates that these effects are strong evidence of change over time with CBTp⁴⁷.

Discussion

We aimed to develop and validate a short version of the CHOICE measure for use in research and clinical practice, with a specific view to it being sensitive and suitable for use over short-time scales and on a sessional basis. A one-page version (CHOICE-SF) was developed from the original severity scale, containing 11 items + 1 personal goal, which retained a clear single factor structure, was highly sensitive to change and showed high internal consistency, validity and

utility for research and clinical practice, as evidenced by its already rapid adoption in a broad range of contexts^{11, 49-64}.

The CHOICE-SF continues to incorporate both cognitive and coping outcomes that are amenable to change with CBTp, as well as well-being outcomes such as peace of mind. The single factor structure was stable across 2 datasets from different clinics in different mental health services. It correlated closely with affect and quality of life, but not delusions and voices measures, and as such supports its discriminant validity from positive symptom measures.

Since the development of the CHOICE-SF it has already been used in six recent or on-going trials^{11, 49-53}, three pilot-feasibility studies⁵⁴⁻⁵⁶, two case studies⁵⁷⁻⁵⁸, one case series⁵⁹ and five observational studies⁶⁰⁻⁶⁴. However, as noted by Stevens and colleagues⁶⁴, no psychometric properties have been available for this short form. Fornells-Ambroio *et al.*⁶¹ used the CHOICE-SF at every session in an IAPT-SMI demonstration site for people with psychosis. The authors found that the CHOICE-SF was well received, with 71% (n = 64) of clients surveyed at the end of therapy reporting it to be actively helpful. Qualitative analysis found that using the CHOICE-SF was helpful for monitoring improvements although it could be less helpful when progress was not being made. Furthermore, the goal-setting item in the CHOICE-SF was particularly valued by service users⁶¹. In a further paper from the same IAPT-SMI site, the authors reported that paired completion rates i.e., a minimum of two CHOICE-SF being completed over the course of therapy, were high at 97%⁶⁰. Interestingly this paper also showed that 77% of patients showed some improvement in CHOICE score following CBTp and 55% showed significant reliable change. These figures are highly consistent with those reported in the current paper where 82%

of participants showed some improvement and 53% showed reliable change. These studies show that the CHOICE-SF can be implemented and is acceptable and successful in demonstrating reliable change as a routine outcome measure. It can be used within clinical services, including in an IAPT-SMI demonstration site, and in research trials that evaluate psychological therapies for a range of issues including paranoia, sleep, worry and self-confidence.

The study has several strengths. We have validated the psychometric properties in two transdiagnostic participant populations, one incorporating psychosis symptoms and the second being voice hearers specifically, with different gender distribution. This demonstrates that the measure is valid and sensitive to change in a mixed sample of people with severe mental illness, including borderline and emotionally unstable personality disorders, complex trauma and depression as well as psychosis. Furthermore, people from black Caribbean or African populations are 2.4 to 14.4 times more likely to develop psychosis compared to other ethnic groups⁶⁵⁻⁶⁶. This ethnic variation is captured in the initial sample where 26% of service users were black Caribbean or African, this suggesting that the CHOICE-SF can be used across a mixed, heterogeneous population. It has similar internal consistency and validity, but enhanced sensitivity to change compared to the original measure, and facilitates a focus on other aspects of change besides positive symptom. It retains a personal goal item which is liked by service users, valuable in shaping therapy focus, and particularly sensitive to change. Although we have not directly compared acceptability and ease of use between CHOICE and CHOICE-SF, the latter is much shorter, and simpler to complete and score, comprising only one sub-scale, making it highly valuable for use in research and routine clinical services.

In terms of limitations, the initial item selection, internal consistency and construct validity of the CHOICE-SF were calculated in a comparatively small sample. Item selection was informed by effect sizes which are not influenced by sample size, and although small samples, can lead to biases in sample selection, the current study utilised an unselected heterogeneous clinical sample, with high ecological validity. The sample size may have contributed to the lack of significant correlation with psychosis symptoms, in contrast to quality of life and emotional symptoms. The low correlation values with psychosis symptoms, are however, in line with the recovery and CBTp literature, and with our previous study, where psychosis symptoms are not necessarily related to well-being or to important CBTp outcomes. Black African and Caribbean service users were slightly under-represented in the secondary validation sample (2% compared to 3% in the general population)⁶⁷ with some under-representation of Asian populations in both samples, (General population = 6.9% vs Initial validation = 2.90% and Baseline secondary validation sample = 4%).

Conclusions

The CHOICE-SF is an 11-item patient reported service-user led psychological recovery outcome measure with high validity, internal consistency and sensitivity to change, with an additional item for a personal goal, which has been found to be highly regarded by service users⁶¹. It is applicable to a broad and heterogeneous service user population and can be employed on a session-by-session basis to evaluate psychological therapy outcomes for Severe Mental Illness.

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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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