Increasing access to CBT for psychosis patients: a randomized controlled trial evaluating brief, targeted CBT for distressing voices delivered by Assistant Psychologists

GiVE3

Statistical Analysis Plan

Trial registration number: 12748453. Registered on 28 September 2022.

SAP version: 1.0 20.08.2024

Protocol version: 7.0 30.06.2023

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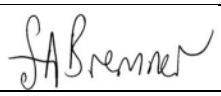
Signature	
Date	20th August 2024
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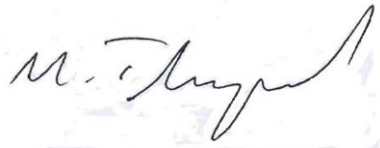
Signature	
Date	20th August 2024

Contents

1. SAP revision history

Version updated	Updated version number	Summary of changes	Author of changes	Date

2. Abbreviations

AP	Assistant Psychologist
ADSUS	Adult Service Use Schedule
BAVQ-R	Beliefs About Voices Questionnaire - Revised
BCSS	Brief Core Schema Scale
CBT	Cognitive Behaviour Therapy
CC/LP	Care Co-ordinator/Lead Practitioner
CHOICE	Choice of Outcome in CBT for psychosEs
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CSRI-UK	Client Service Receipt Inventory
CTU	Clinical Trials Unit
EQ-5D-5L	The EuroQol standardized instrument for measuring generic health status, version 5
GCP	Good Clinical Practice
HADS	Hospital Anxiety and Depression Scale

ICD10	International Classification of Diseases 10th Edition
LEAP	Lived Experience Advisory Panel
NICE	National Institute for Health & Care Excellence
NRES	National Research Ethics Service
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PSYRATS-AH	Psychotic Symptoms Rating Scale – Auditory Hallucination
RA	Research Assistant
R&D	Research & Development
RCT	Randomised Controlled Trial
SF-12	Short Form - 12
TAU	Treatment as Usual
TM	Trial Manager
TS	Trial Statistician
TSC	Trial Steering Committee

3. Introduction

3.1 Background and rationale

The National Institute for Health and Care Excellence (NICE) recommends that Cognitive Behaviour Therapy for psychosis (CBTp) is offered to all patients with a psychosis diagnosis. However, only a minority of psychosis patients in England and Wales are offered CBTp. This is attributable, in part, to the resource-intensive nature of CBTp. One response to this problem has been the development of CBTp in brief formats that are targeted at a single symptom and the mechanisms that maintain distress. We have developed a brief form of CBTp for distressing voices called Guided self-help CBT for voices (also known as the GiVE intervention). We have reported preliminary evidence for the effectiveness of the GiVE intervention when delivered by highly trained therapists (Clinical Psychologists). We have also demonstrated the acceptability and feasibility of conducting an adequately powered Randomised Controlled Trial (RCT) of the GiVE intervention when delivered by briefly trained therapists (Assistant Psychologists).

This current study will evaluate the clinical and cost effectiveness of the GiVE intervention using an adequately powered Randomised Controlled Trial (RCT). Our findings will tell us if the GiVE intervention is helpful to people with a diagnosis of psychosis who are distressed by hearing voices, when delivered by Assistant Psychologists.

Study objectives

To evaluate the clinical and cost effectiveness of the GiVE intervention, a brief, targeted CBT-informed intervention for distressing voices delivered by Assistant Psychologists.

4. Study methods

4.1 Study design

Pragmatic study, two parallel groups, superiority RCT comparing the new intervention and treatment as usual (GiVE) and treatment as usual alone (TAU);

4.2 Randomisation

1:1, Stratified by site (Manchester/Sussex/Cumbria) in randomly permuted blocks, using REDcap.

4.3 Sample size

130 participants i.e. 65 per group implying a caseload of between 10 and 11 participants per therapist over the course of the trial.

4.4 Framework

This is a superiority RCT trial. A hypothesis test will be used to test the superiority of GiVE over TAU.

4.5 Statistical interim analyses and stopping guidance

4.5.1 Interim analyses
No planned interim analyses

4.5.2 Early stopping guidelines
n/a

4.6 Timing of final analysis
All at once in August/September 2024

4.7 Timing of outcome assessments
Baseline (pre-randomisation – Time 0), 16 weeks (post randomisation – Time 1) and 28 weeks (follow-up – Time 2)

5. Statistical principles

5.1 Confidence intervals and p values
95% confidence intervals will be presented for all unstandardised treatment effect estimates for clinical outcomes. 95% confidence intervals will not be presented for Cohen's d standardised effect sizes.

Tests will be significant at the 5% alpha level.

No adjustment for multiplicity because a primary outcome has been stated and all other outcomes are secondary.

5.2 Adherence and protocol deviations
A summary (count & percentage) of participants within the GiVE arm who reach the point of therapy 'exposure' by attending at least six of ten therapy sessions, will be provided.

A tabulation of protocol deviations will be provided.

5.3 Analysis populations
All analyses will be conducted according to intention-to-treat principles i.e. the sample is composed of all participants with observed data for primary and secondary outcomes and will be analysed as per their randomisation group allocation.

We will also conduct a complier average causal effect (CACE)(Dunn et al, 2005, 2015) analysis of the primary outcome defining compliers as participants who had at least 6 out of 10 GiVE sessions).

Participants who withdraw consent for their data to be included will be excluded from all analyses.

All included participants will be analysed for safety.

6. Study population

6.1 Screening data

Summary of screening data count and screen failures. Data to be presented as part of the CONSORT flow diagram.

6.2 Eligibility criteria

6.2.1. Inclusion criteria

1. In contact with Secondary Care Mental Health Services (under the care of a mental health team within one of the recruiting Trusts)
2. Have a clinician-reported diagnosis of psychosis (including schizophrenia spectrum disorder [ICD10 F20–29] or affective disorder with psychotic symptoms [ICD-10 F30–39, subcategories with psychotic symptoms])
3. Aged 18 or over
4. Willing to provide informed consent
5. Experiencing current voice hearing; this will be operationalised by participants having a score of at least 1 on item 1 ('Frequently') on the Psychotic Symptoms Rating Scale—Auditory Hallucinations Scale (PSYRATS-AH) at the time of consent—indicating that the participant has experienced at least one episode of voice hearing in the past week
6. Scoring 3 or 4 (rated on a 0–4 scale) on either the intensity of distress item or the amount of distress item on PSYRATS-AH at the time of consent.

6.2.2. Exclusion criteria

1. Established organic cause for distressing voices
2. Primary diagnosis of substance misuse
3. Currently detained in hospital under a section of the Mental Health Act
4. Having completed a full course (minimum of 16 h) of CBTp for psychotic symptoms during the past year
5. Immediate and serious risk to self or others (assessed at the point of referral/eligibility review)

If inclusion and exclusion criteria are met, every effort will be made to include and support the participation of patients who experience challenges with respect to language and literacy. This will include the use of the translation and literacy services that are routinely available within the clinical services of the host sites and the informal support that is available within the participant's network. The recruitment resources will be available in Easy Read versions.

6.3 Recruitment

Information to be presented on the CONSORT flow diagram.

6.4 Withdrawal/follow up

Level of withdrawal (from intervention/from assessments), timing and reason to be presented on the CONSORT flow diagram.

6.5 Baseline participant characteristics

Baseline characteristics will be summarised by arm and overall.

Participant Characteristic	Summary	Comments
Age in years	mean (s.d.)	Also check min and max scores for data quality checking purposes only
Gender	count (%)	
Employment	count (%)	Working/not working
Marital status	count (%)	In a relationship/not in a relationship
Birth country	count (%)	
First language	count (%)	
Number children under 18	count (%)	
Number children over 18	count (%)	
Ethnicity	count (%)	Ethnic minority broken down by broad categories.
Education	count (%)	
Qualification	count (%)	
Voices onset (age years)	mean (s.d.) min max	
Medication yes/no from CSRI	count (%)	

7. Analysis

7.1 Outcome definitions

Clinical Outcome	Comments All scores are totals unless stated; high score is worse unless stated; ranges in the template in Appendix 1
PSYRATS-AH DISTRESS	The 5-item 'distress' subscale measures the impact that voices have on the individual and will be the primary outcome ◦ The subscale is an observer rated measure that consists of 5 items
PSYRATS-AH TOTAL	11 items - observer rated on a 5-point scale Evaluate the 4 subscales and the total
HADS	14 items 2 scales – Anxiety and Depression Multiple choice
CHOICE	12 items - Likert scale rating from 0 (worst) to 10 (best) *Score is the mean of the first 11 items*
BCSS	12 items - using YES or NO options and a 4-point Likert scale 2 scales - Positive and negative beliefs higher numbers are a greater endorsement of a schema
BAVQ-R	14 items - Likert scale using the options: disagree, unsure, slightly agree strongly agree - higher numbers are a greater endorsement The 14-item version of this measure will be used to capture 'persecutory beliefs' and 'benevolent beliefs'.
Approve – Voices	15-item measure assesses the styles of relating to voices across three subscales—assertive (high is good), aggressive (high is worse) and passive (high is worse).

Approve – Social	15-item measure assesses the styles of relating to other people across three subscales—assertive (high is good), aggressive (high is worse) and passive (high is worse).
Revised Green Paranoid Thoughts Scale	18 items – Parts A (reference - 8 items) and B (persecution - 10 items), each using a 5-point Likert scale with anchors of not at all (0) and totally (4): The R-GPTS score ranges are: average (Reference: 0-9; Persecution: 0-5); elevated (Reference: 10-15; Persecution: 6-10); moderately severe (Reference: 16-20; Persecution:11-17); severe (Reference: 21-24; Persecution: 18-27); and very severe (Reference: 25+; Persecution: 28+)
EQ-5D-5L	(high is good) Use EQ-5D-5L cross walk calculator takes account of the missing data https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/valuation-standard-value-sets/crosswalk-index-value-calculator/
SF-12	(high is good) SF-12 calculator takes account of the missing data

7.2 Analysis methods

The flow of participants through the trial will be shown on a CONSORT Statement 2010 flowchart (Schulz et al, 2010).

Summary statistics will be presented by randomised group for each time point (baseline, 16 weeks and 28 weeks). Normally distributed variables will be described by their means and SDs, skewed continuous variables by their medians and interquartile ranges and categorical variables by the frequency and proportion in each category. Proportion of items missing and the proportion of participants that have a score for each outcome measure will be reported.

The primary analysis will be conducted using a mixed effects model with clustering by therapist in the intervention group only and control participants forming their own clusters of size 1. We will include fixed effects for PSYRATS-AH Distress at baseline, the stratification variable (site: Manchester, Cumbria, Sussex), allocation (GiVE, TAU) and time (16 (T1) and 28 (T2) weeks); a level-three random effect for therapist/control participant and a level-two random effect to account for repeated observations within

participants will be included. A small sample correction (Satterthwaite's) will be applied due to the small number of therapists. We will report the difference in mean PSYRATS-AH Distress between arms, its 95% confidence interval and p-value at each time point (16 weeks and 28 weeks) adjusted for baseline. Statistical significance is set at the 5% level. Secondary outcomes will be analysed using mixed effects models appropriate to outcome distribution controlling for baseline voice hearing distress (PSYRATS-AH) and including the same covariates and random effects as for the primary analysis.

Standardised (Cohen's d) treatment effect sizes for each outcome will be calculated by dividing the between-group unstandardised effect estimate by the baseline pooled standard deviation.

In addition to the analyses for all clinical outcomes, the between-group differences for the primary outcome will be assessed in the context of whether the minimal clinically important difference (MCID) is contained within the 95% confidence intervals where PSYRATS-AH Distress scale of MCID is a 3-point reduction.

For each variable, the amount of missing data will be reported and the missing data mechanism will be explored to check if it can be considered Missing at Random (MAR). If there is ≥ 5% missing data and the data is considered MAR then we will use multiple imputation to address this and produce an adjusted analysis for each outcome as a sensitivity analysis.

We will also conduct a complier average causal effect (CACE) (Dunn et al, 2015) analysis of the primary outcome defining compliers as participants who had at least 6 out of 10 GiVE sessions). We will use a Structural Equation Model (SEM) (Troncoso & Morales-Gómez, 2022) with treatment assignment as the instrument for treatment received. The model will adjust for covariates in the same way as the primary analysis. We will present the effect estimate, its 95% confidence interval and p-value for the test of no treatment effect.

Participants who withdraw consent for their data to be included will be excluded from all analyses.

All included participant data will be analysed for safety.

7.3 Additional analyses

We will do sub-analyses of the primary outcome by Sex and by Ethnicity by fitting an interaction term between the subgroup variable and treatment group. Summary data for between group differences will be provided for each category. 95% confidence

intervals and p-values will be provided for estimated treatment effect sizes. Findings should be treated with caution as sub-analyses may be underpowered.

7.4 Harms

Summary of adverse events/reactions and serious adverse events/reactions by each arm.

7.5 Statistical software

Stata v18 (StataCorp, 2023) will be used for all analyses

8. References

Dunn G, Maracy M, Tomenson B. Estimating treatment effects from randomized clinical trials with noncompliance and loss to follow-up: the role of instrumental variable methods. Stat Methods Med Res. 2005 Aug;14(4):369-95. doi: 10.1191/0962280205sm403oa. PMID: 16178138.

Dunn G, Emsley R, Liu H, Landau S, Green J, White I, Pickles A. Evaluation and validation of social and psychological markers in randomised trials of complex interventions in mental health: a methodological research programme. Health Technol Assess. 2015 Nov;19(93):1-115, v-vi. doi: 10.3310/hta19930. PMID: 26560448; PMCID: PMC4781463.

Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Trials. 2010;11:32. PMID: 20334632

StataCorp. 2023. *Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC.*

Troncoso P, Morales-Gómez A. (2022) Estimating the complier average causal effect via a latent class approach using gsem. The Stata Journal 22:404-415.

Trial Master File, Statistical Master File & Data Collection Tools stored on SPFT Bdrive

B:\THERAPIES\RESEARCH & DEVELOPMENT\Research Studies\Non-Commercial Studies\CSP\IRAS 312765 Hayward M (GIVE 3)

B:\THERAPIES\RESEARCH & DEVELOPMENT\Research Studies\Non-Commercial Studies\CSP\IRAS 312765 Hayward M (GIVE 3)\11.0 Data Management

B:\THERAPIES\RESEARCH & DEVELOPMENT\Research Studies\Non-Commercial Studies\CSP\IRAS 312765 Hayward M (GIVE 3)\11.0 Data Management\11.7 Data Collection Tools

Appendix 1: The following will be presented by time point, trial arm and overall

Clinical Outcome	Score Range	Whether Normally Distributed in feasibility study*	N	Mean	S.D.	25th pc'tile	median	75th pc'tile	IQR
PSYRATS: Distress	0-20	Yes							
PSYRATS: Frequency	0-12	Yes							
PSYRATS: Loudness	0-4	Yes							
PSYRATS: Attribution	0-8	Yes							
PSYRATS: Total	0-44	Yes							
HADS: Depression	0-21	Yes							
HADS: Anxiety	0-21	Yes							
CHOICE: Mean	0-10	Yes							
CHOICE: Goal Rating	0-10	Yes							
BCSS: Negative Self	0-24	No							
BCSS: Positive Self	0-24	No							
BAVQ: Persecutory	0-27	Yes							
BAVQ: Benevolence	0-15	No							
Approve: Voices	0-50								
Approve: Voices	0-50								
Approve: Voices	0-50								
Approve: Social	0-50								
Approve: Social	0-50								
Approve: Social	0-50								
Revised Green Paranoid Thought Scale: Reference	0-32								

Revised Green Paranoid Thought Scale: Persecution	0-40	
EQ_5D_5L: Value Set	-0.594-1	No
EQ_5D_5L: Visual Analogue Scale	0-100	Yes
SF12:Physical Function	0-100	No
SF12:Role Physical	0-100	No
SF12:Bodily Pain	0-100	No
SF12:General Health	0-100	No
SF12:Vitality	0-100	No
SF12:Social Functioning	0-100	Yes
SF12:Role Emotional	0-100	No
SF12:Mental Health	0-100	Yes
SF12:Physical Component Summary	0-100	No
SF12:Mental Component summary	0-100	Yes

Appendix 2: Data dictionary

Variables: 316 22 Jan 2024 16:00

Variable name	Storage type	Display format	Value label	Variable label
study_number	str3	%9s		Study Number
record_id	str5	%9s		Record ID
visit	float	%9.0g	visit	
info_dt	int	%dM_d,_CY		Date of Assessment
info_paper	int	%42.0g	info_paper_	How was this data collected?
info_1	int	%8.0g		Q1 What is your age?
info_2	int	%17.0g	info_2_	Q2 What is your sex? (We will ask you about your gender identity next)
info_3a	int	%50.0g	info_3a_	Q3 How would you describe your gender identity?

```
info_3_1        byte    %8.0g                 Q3.1 Please provide details if you
                                                selected I identify as another term
info_4          int     %17.0g      info_4_   Q4 Do you identify as Transgender?
info_5          int     %27.0g      info_5_   Q5 What is your marital status?
info_6          int     %76.0g      info_6_   Q6 Which of the folowing options best
                                                describes your sexual orientation?
info_6_1        str17   %17s                  Q6.1 Please provide details if you
                                                selected I use another term
info_7          str17   %17s                  Q7 What is your first language?
info_8          int     %66.0g      info_8_   Q8 Which of these ethnic groups best
                                                describes you?
info_8_1        str23   %23s                  Q8.1 If you ticked other background
or
                                                other ethnic group, please describe
info_9          int     %49.0g      info_9_   Q9 Please indicate which of the
                                                following best describes your
                                                highest educationa
info_10         int     %17.0g      info_10_  Q10 Are your day-to-day activities
                                                limited due to being a person with
a
                                                disabili
info_11         int     %99.0g      info_11_  Q11 Which category best describes
your
                                                religion or belief?
info_11_1       str80   %80s                  Q11.1 If you ticked other religion or
                                                belief, please describe
info_12         int     %30.0g      info_12_  Q12 Do you have a child or children
                                                that lives in the same household as
                                                you?
info_13         int     %51.0g      info_13_  Q13 Do you look after, or give any
                                                help, care or support to, anyone
                                                because they
info_14         int     %21.0g      info_14_  Q14 What is your annual household
                                                income?
information_a~e byte    %10.0g      information_about_you_complete_
                                              Complete?
psy_dt          int     %dM_d,_CY             Assessment date
psy_paper       int     %42.0g      psy_paper_
                                              How was this data collected?
psy_1           int     %96.0g      psy_1_    1. Frequency Probing questions How
                                                often have you heard your voices
                                                over the la
psy_2           int     %49.0g      psy_2_    2. Duration Probing questions When
you
                                                have heard your voices over the
last
                                                week
psy_3           int     %98.0g      psy_3_    3. Location Probing questions When
you
                                                have heard your voices over the
last
                                                week
psy_4           int     %35.0g      psy_4_    4. Loudness Probing questions How
loud
                                                are your voices? Are they louder
                                                than my
psy_5           int     %96.0g      psy_5_    5. Beliefs regarding the origin of
```

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                                                  voices Probing questions What do
you
                                                  think ha
psy_6           int     %70.0g      psy_6_      6. Amount of negative content of
                                                  voices Probing questions Do you
                                                  think that your
psy_7           int     %162.0g     psy_7_      7. Degree of negative content Probing
                                                  questions Can you tell me a bit
                                                  about what
psy_8           int     %68.0g      psy_8_      8. Amount of distress Probing
                                                  questions Have you found your
voices
                                                  to be distres
psy_9           int     %78.0g      psy_9_      9. Intensity of distress Probing
                                                  questions Over the last week when
                                                  your voices h
psy_10          int     %358.0g     psy_10_     10. Disruption to life caused by
                                                  voices Probing questions How much
                                                  disruption ha
psy_11          int     %176.0g     psy_11_     11. Controllability of voices Probing
                                                  questions What control had you had
                                                  over yo
psyratsah_com~e byte    %10.0g      psyratsah_complete_
                                                  Complete?
ic_paper        byte    %42.0g      ic_paper_
                                                  How was this data collected?
dob             int     %dM_d,_CY               Participant date of birth
ic_sign         byte    %39.0g      ic_sign_    Has the participant given Informed
                                                  Consent?
ic_dt           int     %dM_d,_CY               Date Informed Consent was given
inc_1           byte    %8.0g       inc_1_      1.In contact with Secondary Care
                                                  Mental Health Services (under the
                                                  care of a Con
inc_2           byte    %8.0g       inc_2_      2. Have a clinician-reported
diagnosis
                                                  of psychosis
inc_3           byte    %8.0g       inc_3_      3. Aged 18 or over
inc_4           byte    %8.0g       inc_4_      4. Willing to provide informed
consent
inc_5           int     %8.0g       inc_5_      5. Experiencing current voice-
hearing;
                                                  this will be operationalised by
                                                  participa
inc_6           int     %8.0g       inc_6_      6. Scoring 3 or 4 (rated on a 0-4
                                                  scale) on either the intensity of
                                                  distress ite
exc_1           byte    %8.0g       exc_1_      1. Established organic cause for
                                                  distressing voices
exc_2           byte    %8.0g       exc_2_      2. Primary diagnosis of substance
                                                  misuse
exc_3           byte    %8.0g       exc_3_      3. Currently detained in hospital
                                                  under a section of the Mental
Health
                                                  Act
exc_4           byte    %8.0g       exc_4_      4. Having completed a full course
                                                  (minimum of 16 hours) of CBTp for
                                                  psychotic sy
exc_5           byte    %8.0g       exc_5_      5. Immediate and serious risk to self
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                                                  or others (assessed at the point of
                                                  referr
eligcon         byte    %8.0g      eligcon_    Has the eligibility of the partcipant
                                                  for inclusion into the study been
                                                  confirme
elig_appdt      int     %dM_d,_CY              Date eligibility was confirmed
elig_reas       byte    %61.0g     elig_reas_
                                               Reason participant is not eligible
elig_reas_oth   str44   %44s                   Other reason, please specify
eligibility_c~e byte    %10.0g     eligibility_complete_
                                               Complete?
rando_dt        int     %dM_d,_CY              Date of randomisation
SITE            str7    %9s
randomisation~e byte    %10.0g     randomisation_complete_
                                               Complete?
PSYRATS_distr~s float   %9.0g
PSYRATS_freq    float   %9.0g
PSYRATS_attr    float   %9.0g
PSYRATS_loud    float   %9.0g
hads_dt         int     %dM_d,_CY              Assessment date
hads_paper      byte    %42.0g     hads_paper_
                                               How was this data collected?
hads_1          byte    %31.0g     hads_1_     1. I feel tense or wound up:
hads_2          byte    %19.0g     hads_2_     2. I feel as if I am slowed down:
hads_3          byte    %18.0g     hads_3_     3. I still enjoy the things I used to
                                                  enjoy:
hads_4          byte    %12.0g     hads_4_     4. I get a sort of frightened feeling
                                                  like butterflies in the stomach:
hads_5          byte    %32.0g     hads_5_     5. I get a sort of frightened feeling
                                                  as if something awful is about to
                                                  happen:
hads_6          byte    %36.0g     hads_6_     6. I have lost interest in my
                                                  appearance:
hads_7          byte    %26.0g     hads_7_     7. I can laugh and see the funny side
                                                  of things:
hads_8          byte    %16.0g     hads_8_     8. I feel restless as I have to be on
                                                  the move:
hads_9          byte    %36.0g     hads_9_     9. Worrying thoughts go through my
                                                  mind:
hads_10         byte    %30.0g     hads_10_    10. I look forward with enjoyment to
                                                  things:
hads_11         int     %16.0g     hads_11_    11. I feel cheerful:
hads_12         byte    %17.0g     hads_12_    12. I get sudden feelings of panic:
hads_13         byte    %10.0g     hads_13_    13. I can sit at ease and feel
                                                  relaxed:
hads_14         int     %11.0g     hads_14_    14. I can enjoy a good book or radio
                                                  or TV programme:
hads_complete   byte    %10.0g     hads_complete_
                                               Complete?
choice_dt       int     %dM_d,_CY              Assessment date
choice_paper    byte    %42.0g     choice_paper_
                                               How was this data collected?
mchoice_1       int     %9.0g      mchoice_1_
                                               1. The ability to approach problems
in
                                                  a variety of ways
mchoice_2       byte    %9.0g      mchoice_2_
                                               2.  Self-confidence
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```
mchoice_3       int     %9.0g      mchoice_3_
                                              3.  Positive ways of relating to
                                                people
mchoice_4       int     %9.0g      mchoice_4_
                                              4.  The ability to question the way I
                                                look at things
mchoice_5       int     %9.0g      mchoice_5_
                                              5.  Ways of dealing with everyday
life
                                                stresses
mchoice_6       int     %9.0g      mchoice_6_
                                              6. Ways of dealing with a crisis
mchoice_7       int     %9.0g      mchoice_7_
                                              7.  Facing my own upsetting thoughts
                                                and feelings
mchoice_8       int     %9.0g      mchoice_8_
                                              8.  Peace of Mind
mchoice_9       byte    %9.0g      mchoice_9_
                                              9.  Understanding myself and my past
mchoice_10      byte    %9.0g      mchoice_10_
                                              10.  Understanding my experiences
                                                (e.g. beliefs, thoughts, voices,
and
                                                related f
mchoice_11      int     %9.0g      mchoice_11_
                                              11.  Positive ways of thinking
mchoice_12      int     %9.0g      mchoice_12_
                                              12. Personal goal (specify below)
choice_12a      str341  %341s                 This is space to write a personal
goal
                                                that you would like to achieve in
                                                therapy
choice_complete byte    %10.0g     choice_complete_
                                              Complete?
bcss_dt         int     %dM_d,_CY             Assessment date
bcss_paper      byte    %42.0g     bcss_paper_
                                              How was this data collected?
bcssm_1         int     %26.0g     bcssm_1_   1. I am unloved
bcssm_2         byte    %26.0g     bcssm_2_   2. I am worthless
bcssm_3         int     %26.0g     bcssm_3_   3. I am weak
bcssm_4         byte    %26.0g     bcssm_4_   4. I am vulnerable
bcssm_5         byte    %26.0g     bcssm_5_   5.  I am bad
bcssm_6         int     %26.0g     bcssm_6_   6.  I am a failure
bcssm_7         byte    %26.0g     bcssm_7_   7. I am respected
bcssm_8         int     %26.0g     bcssm_8_   8. I am valuable
bcssm_9         int     %26.0g     bcssm_9_   9.  I am talented
bcssm_10        byte    %26.0g     bcssm_10_
                                              10. I am successful
bcssm_11        byte    %26.0g     bcssm_11_
                                              11. I am good
bcssm_12        byte    %26.0g     bcssm_12_
                                              12. I am interesting
brief_core_sc~0 byte    %10.0g     brief_core_schema_sc_v_0_
                                              Complete?
approve_dt      int     %dM_d,_CY             Assessment date
approve_paper   byte    %42.0g     approve_paper_
                                              How was this data collected?
appvoices_1     int     %21.0g     appvoices_1_
```

```
                                                  1. Telling them to shut up
appvoices_2     int     %21.0g     appvoices_2_
                                                  2. Giving in
appvoices_3     int     %21.0g     appvoices_3_
                                                  3. Shouting and screaming
appvoices_4     int     %21.0g     appvoices_4_
                                                  4. Hearing what they are saying but
                                                    also stating my own views
appvoices_5     int     %21.0g     appvoices_5_
                                                  5. Standing up for myself
appvoices_6     int     %21.0g     appvoices_6_
                                                  6. Swearing at them
appvoices_7     int     %21.0g     appvoices_7_
                                                  7. Repeating my own opinion if they
                                                    dont listen the first time
appvoices_8     int     %21.0g     appvoices_8_
                                                  8. Yelling at them
appvoices_9     int     %21.0g     appvoices_9_
                                                  9. Presenting and defending my own
                                                    view
appvoices_10    int     %21.0g     appvoices_10_
                                                  10. Finding myself at their mercy
appvoices_11    int     %21.0g     appvoices_11_
                                                  11.  Shouting out loud at them
appvoices_12    int     %21.0g     appvoices_12_
                                                  12. Letting them know that I wish to
                                                    be left in peace right now
appvoices_13    int     %21.0g     appvoices_13_
                                                  13.  Allowing them to get on top of
me
appvoices_14    int     %21.0g     appvoices_14_
                                                  14.  Telling myself they are right
                                                    even though I dont believe they are
                                                    right
appvoices_15    int     %21.0g     appvoices_15_
                                                  15.  Doing what they want
approve_voice~e byte    %10.0g     approve_voices_complete_
                                                  Complete?
bavq_dt         int     %dM_d,_CY            Assessment date
bavq_paper      byte    %42.0g     bavq_paper_
                                                  How was this data collected?
bavq_1          int     %14.0g     bavq_1_    1.  My voice is punishing me for
                                                    something I have done
bavq_2          int     %14.0g     bavq_2_    2. My voice wants to help me
bavq_3          int     %14.0g     bavq_3_    3. My voice is persecuting me for no
                                                    good reason
bavq_4          int     %14.0g     bavq_4_    4. My voice wants to protect me
bavq_5          int     %14.0g     bavq_5_    5. My voice is evil
bavq_6          int     %14.0g     bavq_6_    6. My voice is helping to keep me
sane
babq_7          int     %14.0g     babq_7_    7.  My voice makes me do things I
                                                    really dont want to do
bavq_8          int     %14.0g     bavq_8_    8.  My voice wants to harm me
bavq_9          int     %14.0g     bavq_9_    9.  My voice wants me to do bad
things
bavq_10         int     %14.0g     bavq_10_   10. My voice is helping me to achieve
                                                    my goal in life
bavq_11         int     %14.0g     bavq_11_   11.  My voice will harm or kill me if
```

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                                                  I disobey or resist it
bavq_12         int     %14.0g     bavq_12_   12. My voice is trying to corrupt or
                                                  destroy me
bavq_13         int     %14.0g     bavq_13_   13. I am grateful for my voice
bavq_14         int     %14.0g     bavq_14_   14. My voice rules my life
beliefs_about~1 byte    %10.0g     beliefs_about_voices_v_1_
                                                  Complete?
appsoc_dt       int     %dM_d,_CY              Assessment date
appsoc_paper    byte    %42.0g     appsoc_paper_
                                                  How was this data collected?
appsocm_1       int     %21.0g     appsocm_1_
                                                  1.  Telling them to shut up
appsocm_2       int     %21.0g     appsocm_2_
                                                  2.  Giving in
appsocm_3       int     %21.0g     appsocm_3_
                                                  3.  Shouting and screaming
appsocm_4       int     %21.0g     appsocm_4_
                                                  4.  Hearing what they are saying but
                                                    also stating my own views
appsocm_5       int     %21.0g     appsocm_5_
                                                  5.  Standing up for myself
appsocm_6       int     %21.0g     appsocm_6_
                                                  6.  Swearing at them
appsocm_7       int     %21.0g     appsocm_7_
                                                  7.  Repeating my own opinion if they
                                                    dont listen the first time
appsocm_8       int     %21.0g     appsocm_8_
                                                  8.  Yelling at them
appsocm_9       int     %21.0g     appsocm_9_
                                                  9.  Presenting and defending my own
                                                    view
appsocm_10      int     %21.0g     appsocm_10_
                                                  10.  Finding myself at their mercy
appsocm_11      int     %21.0g     appsocm_11_
                                                  11.  Shouting out loud at them
appsocm_12      int     %21.0g     appsocm_12_
                                                  12.  Letting them know that I wish to
                                                    be left in peace right now
appsocm_13      int     %21.0g     appsocm_13_
                                                  13.  Allowing them to get on top of
me
appsocm_14      int     %21.0g     appsocm_14_
                                                  14.  Telling myself they are right
                                                    even though I dont believe they are
                                                    right
appsocm_15      int     %21.0g     appsocm_15_
                                                  15.  Doing what they want
approve_socia~e byte    %10.0g     approve_social_complete_
                                                  Complete?
green_dt        int     %dM_d,_CY              Assessment date
green_paper     byte    %42.0g     green_paper_
                                                  How was this data collected?
green_1         int     %15.0g     green_1_   1.  I spent time thinking about
                                                    friends gossiping about me
green_2         byte    %15.0g     green_2_   2. I often heard people referring to
                                                    me
green_3         int     %15.0g     green_3_   3.  I have been upset by friends and
                                                    colleagues judging me critically
```

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green_4         byte    %15.0g     green_4_   4. People definitely laughed at me
                                                behind my back
green_5         int     %15.0g     green_5_   5. I have been thinking a lot about
                                                people avoiding me
green_6         int     %15.0g     green_6_   6. People have been dropping hints
for
                                                me
green_7         int     %15.0g     green_7_   7. I believed that certain people
were
                                                not what they seemed
green_8         int     %15.0g     green_8_   8. People talking about me behind my
                                                back upset me
green_b1        int     %15.0g     green_b1_
                                              1. Certain individuals have had it in
                                                for me
green_b2        int     %15.0g     green_b2_
                                              2. People wanted me to feel
                                                threatened, so they stared at me
green_b3        byte    %15.0g     green_b3_
                                              3. I was certain people did things in
                                                order to annoy me
green_b4        int     %15.0g     green_b4_
                                              4. I was convinced there was a
                                                conspiracy against me
green_b5        byte    %15.0g     green_b5_
                                              5. I was sure someone wanted to hurt
                                                me
green_b6        int     %15.0g     green_b6_
                                              6. I couldnt stop thinking about
                                                people wanting to confuse me
green_b7        int     %15.0g     green_b7_
                                              7.  I was distressed by being
                                                persecuted
green_b8        int     %15.0g     green_b8_
                                              8.  It was difficult to stop thinking
                                                about people wanting to make me
feel
                                                bad
green_b9        int     %15.0g     green_b9_
                                              9.  People have been hostile towards
                                                me on purpose
green_b10       int     %15.0g     green_b10_
                                              10.  I was angry that someone wanted
                                                to hurt me
paranoid_thou~2 byte    %10.0g     paranoid_thoughts_sc_v_2_
                                              Complete?
csri_dt         int     %dM_d,_CY             Assessment date
csri_paper      int     %42.0g     csri_paper_
                                              How was this data collected?
csri_1_1        int     %dM_d,_CY             1.1 Date of birth *Derived from
                                                Eligibility page*
csri_1_2        byte    %17.0g     csri_1_2_
                                              1.2 Sex
csri_1_3        byte    %16.0g     csri_1_3_
                                              1.3 Marital status (from a legal
                                                perspective)
csri_1_4        str30   %30s                   1.4 What is your ethnicity
csri_1_5        str18   %18s                   1.5 Country of birth
```

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csri_1_6        byte    %69.0g     csri_1_6_
                                                1.6 First language
csri_1_7        byte    %8.0g                   1.7 Number of years of schooling in
                                                  general education
csri_1_8        byte    %28.0g     csri_1_8_
                                                1.8 Highest completed level of
                                                  education
csri_1_9___1    byte    %9.0g      csri_1_9___1_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_1_9___2    byte    %9.0g      csri_1_9___2_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_1_9___3    byte    %9.0g      csri_1_9___3_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_1_9___4    byte    %9.0g      csri_1_9___4_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_1_9___5    byte    %9.0g      csri_1_9___5_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_1_9___6    byte    %9.0g      csri_1_9___6_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_1_9___999  byte    %9.0g      csri_1_9___999_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_1_9___888  byte    %9.0g      csri_1_9___888_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_1_9___777  byte    %9.0g      csri_1_9___777_
                                                1.9 What further education or
                                                  vocational training have you
                                                  completed or are you
csri_2_1        int     %39.0g     csri_2_1_
                                                2.1 What is your usual/normal living
                                                  situation now?
csri_2_2        int     %93.0g     csri_2_2_
                                                2.2 What kind of accommodation is it?
csri_3_1oth_2   str24   %24s                    Other (specify):
csri_3_1        byte    %23.0g     csri_3_1_
                                                3.1 What is your employment status?
csri_3_1sp      str56   %56s                    Other (specify):
csri_3_2        byte    %47.0g     csri_3_2_
                                                3.2 If employed: state occupation
                                                  type:
csri_3_2sp      str42   %42s                    Other (specify):
csri_3_2b       byte    %8.0g                   How many days have you been absent
                                                  from work owing to illness within
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                                                    the last 3
csri_3_3        int     %8.0g                    3.3 If unemployed: Number of weeks
                                                    unemployed within the last 3 months
csri_3_4        int     %8.0g       csri_3_4_
                                                 3.4 Do you receive any state
benefits?
csri_3_4b___1   byte    %9.0g       csri_3_4b___1_
                                                 If yes: What benefits are received?
                                                    (Tick all boxes that apply)
                                                    (choice=Unemploy
csri_3_4b___2   byte    %9.0g       csri_3_4b___2_
                                                 If yes: What benefits are received?
                                                    (Tick all boxes that apply)
                                                    (choice=Sickness
csri_3_4b___3   byte    %9.0g       csri_3_4b___3_
                                                 If yes: What benefits are received?
                                                    (Tick all boxes that apply)
                                                    (choice=Housing)
csri_3_4b___4   byte    %9.0g       csri_3_4b___4_
                                                 If yes: What benefits are received?
                                                    (Tick all boxes that apply)
                                                    (choice=Other be
csri_3_4b___999 byte    %9.0g       csri_3_4b___999_
                                                 If yes: What benefits are received?
                                                    (Tick all boxes that apply)
                                                    (choice=Missed i
csri_3_4b___888 byte    %9.0g       csri_3_4b___888_
                                                 If yes: What benefits are received?
                                                    (Tick all boxes that apply)
                                                    (choice=Not appl
csri_3_4b___777 byte    %9.0g       csri_3_4b___777_
                                                 If yes: What benefits are received?
                                                    (Tick all boxes that apply)
                                                    (choice=Not resp
csri_4_1a_ad    byte    %8.0g                    Acute psychiatric ward: Admissions
csri_4_1a_in    byte    %8.0g                    Acute psychiatric ward: Total number
                                                    of inpatient days (over the last 3
                                                    months)
csri_4_1b_ad    byte    %8.0g                    Psychiatric rehabilitation ward:
                                                    Admissions
csri_4_1b_in    byte    %8.0g                    Psychiatric rehabilitation ward:
                                                    Total number of inpatient days
(over
                                                    the last
csri_4_1c_ad    byte    %8.0g                    Long-stay ward: Admissions
csri_4_1c_in    byte    %8.0g                    Long-stay ward:  Total number of
                                                    inpatient days (over the last 3
                                                    months)
csri_4_1d_ad    byte    %8.0g                    Emergency / crisis centre: Admissions
csri_4_1d_in    byte    %8.0g                    Emergency / crisis centre:  Total
                                                    number of inpatient days (over the
                                                    last 3 mont
csri_4_1e_ad    byte    %8.0g                    General medical ward: Admissions
csri_4_1e_in    byte    %8.0g                    General medical ward:  Total number
of
                                                    inpatient days (over the last 3
                                                    months)
csri_4_1fsp     int     %8.0g                    Other (specify)
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csri_4_1f_ad    int     %8.0g                [csri_4_1fsp]: Admissions
csri_4_1f_in    int     %8.0g                [csri_4_1fsp]:  Total number of
                                               inpatient days (over the last 3
                                               months)
csri_4_2a       byte    %8.0g                Psychiatric outpatient visit Number
of
                                               appointments (over the last 3
                                               months):
csri_4_2b       byte    %8.0g                Other hospital outpatient visit
(incl.
                                               A&E)  Number of appointments (over
                                               the la
csri_4_2c       byte    %8.0g                Day hospital  Number of day
                                               attendances (over the last 3
                                               months):
csri_4_2dsp     str20   %20s                 Other service (specify)
csri_4_2d       int     %8.0g                [csri_4_2dsp]: Number of
                                               appointments/attendances etc
                                               received (over the last 3
csri_4_3a_at    byte    %8.0g                Community mental health centre:
Number
                                               of attendances
csri_4_3a_dur   byte    %8.0g                Community mental health centre:
                                               Average duration of attendance
csri_4_3b_at    byte    %8.0g                Day care centre: Number of
attendances
csri_4_3b_dur   int     %8.0g                Day care centre: Average duration of
                                               attendance
csri_4_3c_at    byte    %8.0g                Group therapy: Number of attendances
csri_4_3c_dur   byte    %8.0g                Group therapy: Average duration of
                                               attendance
csri_4_3d_at    byte    %8.0g                Sheltered workshop: Number of
                                               attendances
csri_4_3d_dur   byte    %8.0g                Sheltered workshop: Average duration
                                               of attendance
csri_4_3e_at    byte    %8.0g                Specialist education: Number of
                                               attendances
csri_4_3e_dur   byte    %8.0g                Specialist education: Average
duration
                                               of attendance
csri_4_3fsp     str62   %62s                 Other service (specify)
csri_4_3f_at    byte    %8.0g                [csri_4_3fsp]: Number of attendances
csri_4_3f_dur   byte    %8.0g                [csri_4_3fsp]: Average duration of
                                               attendance
csri_4_4a       byte    %10.0g    csri_4_4a_
                                             Psychiatrist
csri_4_4b       int     %10.0g    csri_4_4b_
                                             Psychologist
csri_4_4c       byte    %10.0g    csri_4_4c_
                                             Primary care physician
csri_4_4d       byte    %10.0g    csri_4_4d_
                                             District nurse
csri_4_4e       byte    %10.0g    csri_4_4e_
                                             Community psychiatric nurse / case
                                               manager
csri_4_4f       byte    %10.0g    csri_4_4f_
                                             Social worker
csri_4_4g       byte    %10.0g    csri_4_4g_
```

				Occupational therapist
csri_4_4h	int	%10.0g	csri_4_4h_	
				Home help / care worker
csri_4_4i	byte	%10.0g	csri_4_4i_	
				Other
csri_4_4j	int	%10.0g	csri_4_4j_	
				Other
csri_4_4a_con	byte	%8.0g		Psychiatrist:Total number of contacts over the last 3 months
csri_4_4a_hrs	float	%9.0g		Psychiatrist:Average contact time (hours)
csri_4_4b_con	byte	%8.0g		Psychologist:Total number of contacts over the last 3 months
csri_4_4b_hrs	float	%9.0g		Psychologist:Average contact time (hours)
csri_4_4c_con	byte	%8.0g		Primary care physician:Total number of contacts over the last 3 months
csri_4_4c_hrs	float	%9.0g		Primary care physician:Average contact time (hours)
csri_4_4d_con	int	%8.0g		District nurse:Total number of contacts over the last 3 months
csri_4_4d_hrs	float	%9.0g		District nurse:Average contact time (hours)
csri_4_4e_con	int	%8.0g		Community psychiatric nurse / case manager:Total number of contacts over the las
csri_4_4e_hrs	float	%9.0g		Community psychiatric nurse / case manager:Average contact time (hours)
csri_4_4f_con	byte	%8.0g		Social worker:Total number of contacts over the last 3 months
csri_4_4f_hrs	float	%9.0g		Social worker:Average contact time (hours)
csri_4_4g_con	byte	%8.0g		Occupational therapist:Total number of contacts over the last 3 months
csri_4_4g_hrs	byte	%8.0g		Occupational therapist:Average contact time (hours)
csri_4_4h_con	int	%8.0g		Home help / care worker:Total number of contacts over the last 3 months
csri_4_4h_hrs	float	%9.0g		Home help / care worker:Average contact time (hours)
csri_4_4isp	str64	%64s		Other service (specify)
csri_4_4i_con	byte	%8.0g		[csri_4_4isp]:Total number of contacts over the last 3 months
csri_4_4i_hrs	float	%9.0g		[csri_4_4isp]:Average contact time (hours)
csri_4_4jsp	str34	%34s		Other service (specify)
csri_4_4j_con	byte	%8.0g		[csri_4_4jsp]:Total number of contacts over the last 3 months
csri_4_4j_hrs	float	%9.0g		[csri_4_4jsp]:Average contact time (hours)

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csri_4_5        byte    %8.0g      csri_4_5_
                                              4.5 Over the last 3 months, has the
                                                patient been in contact with the
                                                criminal ju
csri_4_5a       byte    %8.0g                 If yes: How many contacts with the
                                                police (Note: contact = interview
or
                                                stay of
csri_4_5b       byte    %8.0g                 How many nights spent in a police
cell
                                                or prison?
csri_4_5c       byte    %8.0g                 How many psychiatric assessments
                                                whilst in custody?
csri_4_5d       byte    %8.0g                 How many criminal court appearances?
csri_4_5e       byte    %8.0g                 How many civil court appearances?
client_servic~3 byte    %10.0g     client_service_recei_v_3_
                                              Complete?
eq_dt           int     %dM_d,_CY             Assessment date
eq_paper        int     %42.0g     eq_paper_
                                              How was this data collected?
eq_1            int     %41.0g     eq_1_      MOBILITY
eq_2            int     %51.0g     eq_2_      SELF-CARE
eq_3            int     %50.0g     eq_3_      USUAL ACTIVITIES (e.g. work, study,
                                                housework, family or leisure
                                                activities)
eq_4            int     %34.0g     eq_4_      PAIN / DISCOMFORT
eq_5            int     %36.0g     eq_5_      ANXIETY / DEPRESSION
eq5d5l_complete byte    %10.0g     eq5d5l_complete_
                                              Complete?
sf12_dt         int     %dM_d,_CY             Assessment date
sf12_paper      int     %42.0g     sf12_paper_
                                              How was this data collected?
sf12_1          int     %9.0g      sf12_1_    1. In general, would you say your
                                                health is:
sf_12_2         int     %22.0g     sf_12_2_   2a. Moderate activities, such as
                                                moving a table, pushing a vacuum
                                                cleaner, bowli
sf_12_3         int     %22.0g     sf_12_3_   2b. Climbing several flights of
                                                stairs. Does your health now limit
                                                you a lot, li
sf_12_4         int     %20.0g     sf_12_4_   3a. During the past four weeks, how
                                                much of the time have you
                                                accomplished less
sf_12_5         int     %20.0g     sf_12_5_   3b. During the past four weeks, how
                                                much of the time were you limited
in
                                                the kin
sf_12_6         int     %20.0g     sf_12_6_   4a. During the past four weeks, how
                                                much of the time have you
                                                accomplished less
sf_12_7         int     %20.0g     sf_12_7_   4b. During the past four weeks, how
                                                much of the time were you limited
in
                                                the kin
sf_12_8         int     %12.0g     sf_12_8_   5. During the past 4 weeks, how much
                                                did pain interfere with your normal
                                                work (i
sf_12_9         int     %20.0g     sf_12_9_   6a. How much of the time during the
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                                                  past 4 weeks…have you felt calm and
                                                  peaceful
sf_12_10        int     %20.0g     sf_12_10_
                                                  6b. How much of the time during the
                                                  past 4 weeks…did you have a lot of
                                                  energy?
sf_12_11        int     %20.0g     sf_12_11_
                                                  6c. How much of the time during the
                                                  past 4 weeks…have you felt
                                                  downhearted and d
sf_12_12        int     %20.0g     sf_12_12_
                                                  7. How much of the time during the
                                                  past 4 weeks…has your physical
                                                  health or emot
sf12_v2_compl~e byte    %10.0g     sf12_v2_complete_
                                                  Complete?
-------------------------------------------------------------------------------
-
```