Culturally Adapted Family Intervention (CaFI)

Phase 3A: Feasibility Study

STATISTICAL ANALYSIS PLAN

DRAFT V4

1. INTRODUCTION

   This document considers the statistical analysis to be undertaken for the CaFI feasibility study. The purpose of the SAP is to document the statistical analysis of the feasibility study, thereby controlling for statistical analysis bias.

2. OBJECTIVES LISTED IN PROTOCOL

   The objectives of the feasibility study are:

   i. Test the feasibility of delivering Culturally-adapted Family Intervention (CaFI) among African-Caribbean service users in hospital and community settings
   ii. Test the feasibility of recruiting service users, biological families and 'Family Support Members'
   iii. Test the feasibility of delivering the intervention via 'Family Support Members' where biological families are not available
   iv. Assess the acceptability of the intervention to key stakeholders – including service users, their families and mental health professionals
   v. Identify outcome measures for future randomised controlled studies and assess the feasibility of collecting them

3. STUDY DESIGN

   The study design is described in the protocol. In summary, 30 African Caribbean people diagnosed with schizophrenia (10 in each setting, acute wards, rehabilitation wards/units, CMHTs) receive 10 hourly sessions of CaFI. To optimise access to the intervention, where biological families are absent or estranged, we shall create 'proxy families' - Trusted individuals nominated by service users (such as friend, local pastor or key worker) or volunteer Family Support Members (FSM) recruited to the study.

4. INTERVENTION

   During earlier phases of the research study, the team have developed a manual for a culturally-adapted family intervention (CaFI) for African Caribbean people diagnosed with schizophrenia. CaFI involves 10 hourly sessions attended by the service user and their family members/ Family Support Members, delivered by a lead therapist and co-therapist who have received a bespoke training package.

5. DATA

5.1. Recruitment to study - identification, eligibility and consent.

5.2. Baseline characteristics - service users and family members/FSMs

5.3. Therapy delivery - uptake, retention (number completed sessions, intensity - 'therapy window'), and withdrawal data, and characteristics of sessions (attendees, location, duration)

5.4. Therapy acceptability - feedback (collected every session) and therapeutic alliance (session 3)

5.5. Outcome measures - (baseline, post intervention, 3 months post-intervention)

6. STATISTICAL ANALYSIS

6.1. Recruitment to study

6.1.1. Therapist recruitment
- Expected total recruitment
- Actual total recruitment
- Recruitment by Trust

6.1.2. Service user recruitment
- Expected total recruitment
- Actual total recruitment
- Recruitment by Trust (MHSCT, GMW)
- Recruitment by setting (community - CMHT; community – EIS; acute inpatient ward; rehab unit/supported housing; third sector)
- Recruitment by source (Clinical Research Network, CAFI research team, self-referral, referral via care team, CRN Amigos)

6.1.3. Family recruitment
- Expected total recruitment
- Actual total recruitment
- Recruitment by type (biological relatives/FSM nominated/ FSM allocated))
- Number of service users select biological relatives vs. nominated FSMs vs. allocated FSMs

6.2. Pre-recruitment

6.2.1. Approached
- Expected population by Trust (audit clinical information system)
- Actual numbers approached (number of participants to whom recruitment packs were sent)

6.2.2. Ineligible

- Numbers ineligible
- Numbers ineligible by Trust and by setting
- Reasons
- Characteristics of ineligible people where available, including comparison with characteristics of eligible participants

6.2.3. Non-consent
- Numbers not-consenting
- Numbers not-consenting by Trust and by setting
- Reasons(opt out response forms)
- Characteristics of non-consenters where available (opt out response forms)

6.3. Data cleaning
Data cleaning of the data will be conducted to identify inconsistencies and errors. Summary statistics from the data cleaning will be reviewed by the CAFI team to resolve any errors.

6.4. Missing data
Report the frequencies (with percentages) of the items that are missing (baseline characteristics, acceptability, outcomes), with reasons if known. Where data is missing and cannot be obtained we are not planning any imputation.

6.5. Baseline characteristics
Baseline characteristics will be reported as mean/SD/range for continuous variables and number/proportion for categorical variables.

6.6. Therapy delivery
- Number starting therapy [uptake]
- Number of family units (service user and/or relative/FSM) completing treatment (10 sessions) [retention]
  - Number of service users completing treatment (10 sessions)
  - Number of family members/FSMs completing treatment (10 sessions)
  - Number of family units completing treatment by family member type (biological vs. FSM nominated vs. FSM allocated) and setting
  - Number of family units completing treatment by therapist type [psychologist vs. non-psychologist]
- Mean/SD number of sessions completed [retention]
  - Mean/SD number of sessions completed by service user
  - Mean/SD number of sessions completed by family members/FSMs
- Number of service users changing family member/FSM by type and time point
- Mean time to complete treatment [intensity]

- Number of family units completing treatment in therapy window (20 weeks)
- Number of withdrawals/attrition from therapy – total and by session number
- Number of withdrawals/attrition from study – total and by time point (pre-baseline, post-baseline, during therapy, post-therapy)
- Reasons for withdrawal/attrition
- Characteristic of sessions - mean length of session [duration]; number of attendees by participant group; number of sessions by location

6.7. Therapy acceptability
- Overall rates of session acceptability
- Acceptability by lead therapist, therapist pair, session number/ component (1-5), family member/FSM type (nominated versus recruited), setting and by psychologist/non-psychologist.

6.8. Outcome measures

6.8.1. Distribution
Report on the distribution of the outcome measures, including assessment of normality.

6.8.2. Data completeness
- Number of service users/family with complete follow up at each time point.
- Completeness of each separate outcome, at each time point.
- Reasons for incomplete data, if available.
- Report whether able collect the measures from same key worker at FU

6.8.3. Change in outcomes
The study is not powered to estimate changes in health outcomes, and it does not include a control group as comparison.

We are aware of the problem of loss to follow up in mental health trials. We shall prepare for this in a future trial by examining outcomes at points of departure from the trial.

- For continuous outcomes, we will present the trajectories for each individual (from baseline to 3 month follow up) to explore the pattern of missing data. This will inform our strategies for recruitment and retention and our decisions on imputation for a future trial.
- Similarly, for binary outcomes, we will relate the pattern of missing values to the responses given.

- Where we have the choice of two similar outcome measures, we will choose between them for a future trial by comparing variability.

6.9 Adverse events

    6.8.4. Number of adverse events

    6.8.5. Number of serious adverse events

    6.8.6. Number related to intervention

7. Appendices

    7.1.1. List of outcome variables

    7.1.2. Measures with reverse scores

    7.1.3. Figure 1: CONSORT diagram

    7.1.4. Tables 1-4: Data assessment schedules

8. Related documents

- Phase 3B Fidelity Study Protocol
- Phase 3A Feasibility Study Qualitative Analysis Plan
- START in CaFI Protocol
- Rating Relapse Protocol

List of outcome variables

<u>Service user</u>

- PANSS POS SUBSCALE
- PANSS NEG SUBSCALE
- PANSS GEN SUBSCALE
- PANSS TOTAL

- PSP SOCIAL SUBSCALE
- PSP RELATIONS SUBSCALE
- PSP SELF-CARE SUBSCALE
- PSP AGGRESSION SUBSCALE
- PSP TOTAL

- PCS 1 = SINGLE ITEM SCORE
- PCS 2 = SINGLE ITEM SCORE

- BIPQ 1-11 = SINGLE ITEM SCORE
- BIPQ 12 = CATEGORICAL

- EQ5D 1-5 = SINGLE ITEM SCORE

- WAI CV TASK SUBSCALE
- WAI CV BOND SUBSCALE
- WAI CV GOAL SUBSCALE
- WAI CV TOTAL SUBSCALE

Family/FSM

- GHQ TOTAL

- BIPQ 1-15 = SINGLE ITEM SCORE
- BIPQ 16 = CATEGORICAL

- KAPI SYMPTOM
- KAPI CAUSE
- KAPI MED
- KAPI PROGNOSIS
- KAPI MANAGE
- KAPI TOTAL

- EQ5D 1-5 = SINGLE ITEM SCORE
  - Rachel Meacock to compute

Staff

- WAI KWV TASK SUBSCALE
- WAI KWV BOND SUBSCALE
- WAI KWV GOAL SUBSCALE
- WAI KWV TOTAL SUBSCALE

- SES AVAILABILITY
- SES COLLABORATION
- SES HELP-SEEKING
- SES TREATMENT ADHERENCE
- SES TOTAL

Measures with reverse scores

1) **Working Alliance Inventory Client Version– WAIC - SU**

   Reverse scored questions: Q4 and Q10.

   Higher scores = better alliance

1) **Working Alliance Inventory Key Worker Version– WAIK - STAFF**

   Reverse scored questions: Q4 and Q10.

   Higher scores = better alliance

2) **Service Engagement Scale -STAFF**

   Reverse scored questions: Q2, Q5, Q6, Q7, Q9, Q11 and Q12.

   Higher scores = poorer engagement

The scheduling of these assessments is summarised in tables 3 to 6 in the main body of the report