Title: EMPOWER: Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery (Phase 2)

Funded by	National Institute for Health Research – Health Technology Assessment Programme (UK) NHS Greater Glasgow & Clyde National Health and Medical Research Council (Australia)
Sponsors:	
UK	NHS Greater Glasgow & Clyde
Australia	Australian Catholic University

Statistical Analysis Plan for PHASE 2 (Version 1)

This SAP is based as far a is appropriate on guidelines given in JAMA. 2017;318(23):2337-2343. doi:10.1001/jama.2017.18556

1 Administration

TRIAL FULL TITLE	EMPOWER: Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery (Phase 2)
EUDRACT NUMBER	n/a
SAP VERSION	draft
ISRCTN NUMBER	*99559262*
SAP VERSION DATE	Dec 2018
TRIAL STATISTICIAN	Dr Lorna Aucott
TRIAL CHIEF INVESTIGATOR	*Professor Andrew Gumley*
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1.1 SAP Signatures

I give my approval for the attached SAP entitled EMPOWER, dated 16th July 2019

Chief Investigator

Name:

Signature: 

Date: 17 July 2019

Statistician

Name: lorna Aucott

Signature:

Date: 17 July 2019

1.2 Amendment History

SAP version	Protocol version	Section number changed	Description of and reason for change	Date changed

1.3 Contents

1.4 Tables

1.5 Abbreviations and Definitions

Term	Description (using lay language)
App	Mobile telephone application
CHaRT	Centre for Healthcare Randomised Trials
CMHS	Community Mental Health Service
CRCT	Cluster Randomised Controlled Trial
CTU	Clinical Trials Unit
Care Coordinator	Key Worker (UK) or Key Clinician (Australia)
DMEC	Data Monitoring and Ethics Committee
EMPOWER	Early signs monitoring to Prevent relapse in psychosis and pr0mote Wellbeing, Engagement, and Recovery
EWS	Early warning signs
MRC	Medical Research Council
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NHSGG&C	NHS Greater Glasgow & Clyde
NIHR	National Institute for Health Research
PTM	Project team member
RCT	Randomised controlled trial
Service User	Consumer, Patient or person in receipt of mental health services
SSC	Study Steering Committee
TAU	Treatment as usual
CHaRT	Centre for Healthcare Randomised Trials
CI	Chief Investigator
CRF	Case Report Form
DMC	Data Monitoring Committee
HSRU	Health Services Research Unit
SAP	Statistical Analysis Plan

2 Introduction

Relapse in schizophrenia is a major cause of distress and disability amongst patients and their families. Relapse is predicted by changes in symptoms such as anxiety, depression and suspiciousness (so called early warning signs, EWS) and can be used as the basis for timely interventions to prevent relapse and hospitalization. Research shows that interventions focused on EWS can reduce these negative outcomes and enhance recovery. However, the quality of research evidence is poor so that it is not possible to estimate whether these can be applied in routine practice.

2.1 Study Objectives

To establish the feasibility of conducting a definitive Cluster Randomised Controlled Trial (C-RCT) comparing EMPOWER against Treatment As Usual (TAU). We will establish the parameters of the feasibility, acceptability, usability, safety and outcome signals of an intervention as an adjunct to usual care that is easily deliverable in the NHS and Australian community mental health service.

3 Study Methods

3.1 Trial design

This pilot study is a two-arm, parallel groups C-RCT in eight Community Mental Health Services (CMHS), two in Melbourne, Australia, and six in Glasgow.

3.2 Randomisation and Blinding

The unit of randomisation is the CMHT (the cluster). Participating CMHTs will be randomised within stratified pairs to the EMPOWER Relapse Prevention Intervention or to continue their usual approach to care. A statistician the Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen will provide the allocation codes. The two clusters in Australia form a single stratum. The six clusters in Glasgow will be paired based on similarity of catchment area in terms of social deprivation (Carstairs) score or CMHS type (e.g. early intervention service).

3.3 Sample Size and Power Calculation

There was no formal sample size calculation for this feasibility study. The originally the proposed sample size was of 120 service users across 40 care coordinators in eight CMHTs. However, with support from our DMEC (based on DMEC Recruitment Report to DMEC, 27th March 2018) and the Chair of our Trial Steering Committee (Professor David Kingdon), this was revised to a target of n=56 (+13 carers) in the UK and n=30 participants (+3 carers) in Melbourne, a total of n=86 (+16 carers). For a feasibility study this was still deemed sufficient for establishing the feasibility and estimating parameters (including the relevant ICCs for the cluster design) to cautiously inform along with other sources, the design and size of a future definitive, pragmatic, multicentre and multinational CRCT.

3.4 Interim Analyses and Data Monitoring

There are no planned interim analyses for this feasibility study. Reports on safety and recruitment will be sent to DMC and SSC oversight committees at least annually.

3.4.1 Documentation of Interim Reports

The data available at each interim analysis will be preserved, along with all documentation of analysis plans, programming code and reporting provided.

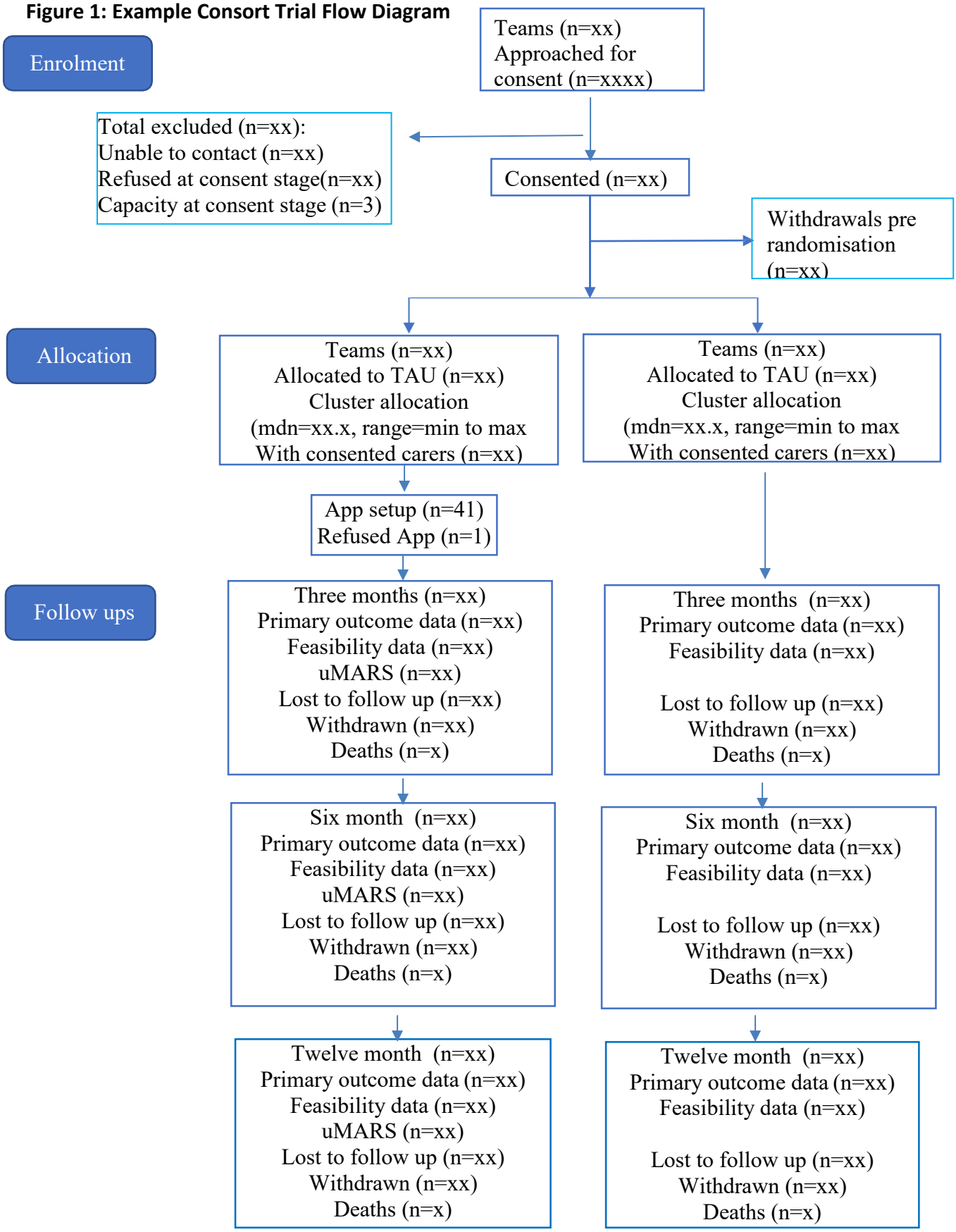
3.5 Timing of final Analyses

A single final analysis will take place at the end of the feasibility study, after all participants have reached their final follow-up.

3.6 Consort Flow

For all participants, outcome assessment will include: the proportion of eligible and willing service users who then consent and the proportion continuing for 3, 6 and 12-months to the end of the study. See example of flow diagram below:

Figure 1: Example Consort Trial Flow Diagram



3.7 Outcome Measurements

3.7.1 Feasibility Outcomes

3.7.1.1 Service user-centred

We will report the frequency of seeking help in relation to EWS; the frequency family member/carer has sought help in response to EWS; and the frequency clinical care has changed in response to EWS at baseline initially and then at 3, 6 and 12-months.

3.7.1.2 Mental Health Staff

We will report self-reported frequency of discussing EWS with care coordinator, frequency of person seeking help in relation to EWS, frequency of care coordinator seeking help in response to EWS and frequency clinical care has changed in response to EWS and as above at baseline then at 3, 6 and 12-months (e.g. appointment brought forward, medication change).

3.7.1.3 Carer

We will report self-reported frequency of discussing EWS with family member/carer, frequency of person seeking help in relation to EWS, frequency of family member/carer seeking help in response to EWS and frequency clinical care has changed in response to EWS at 3, 6 and 12-months (e.g. appointment brought forward, medication change).

3.7.1.4 Acceptability and Usability outcomes– prepared by PTM, verified by statistics team

For those randomised to EMPOWER we will report the length of time participants are willing to use the App and the number completing >33% EWS datasets. We will also report the self-reported frequency of App use, frequency of sharing data with the keyworker, frequency of sharing data with family member / carer and frequency of accessing charts at baseline, 3, 6 and 12-months.

We will also assess self-reported acceptability and usability using an adapted version of the Mobile App Rating Scale (Stoyanov et al. 2016).

3.7.1.5 Safety – prepared by PTM, verified by statistics team

Adverse events will be recorded according to the following categories:

- Adverse events (AE)
- Adverse Device Effect (ADE)
- Serious Adverse Device Effect (SADE)
- Serious Adverse Event (SAE)
- Anticipated Serious Adverse Device Effect (ASADE)
- Unanticipated Serious Adverse Device Effect (USADE)

We will also record Device Deficiencies. Adverse effects and device deficiencies will be reported across the whole study rather than at the separate follow-up timepoints. Other constructs that need to be considered within safety are those derived from the Fear of Recurrence Scale (Forse) namely intrusiveness, awareness, relapse as well as an overall total. This however will be at baseline, 3, 6 and 12-months

3.7.2 Baseline Demographics and Clinical Characteristics

We will present demographic summaries of the service user participants including Remission Status and other clinical characteristics clustered according to Secondary and Mechanism measures, which are described later in Section 3.7.3. Similarly we will present the Carer and Care Coordinator Demographics and their associated measures in their respective tables.

3.7.3 Clinical Outcomes

For this phase, all outcome measures will be assessed, not to compare between arms but more to assess how valid the measures are. None-the-less in addition to the summaries for each, appropriate models (See more detail in the Statistical Analysis Section) will be run and model estimates provided for discussion purposes.

3.7.3.1 Candidate Primary Clinical Outcome for the Main Trial

Relapse over the 12-months follow-up assessed by a reliable and valid criteria developed (during this feasibility) via an adjudication committee of expert clinicians/researchers making independent blinded anonymised ratings of relapse and exacerbations. We will report time to first relapse, number and type of relapse (Relapse, Exacerbation, Unspecified), and severity score derived from the Relapse Assessment Scale (0-7) over 12-months. We will also report number (%) with (a) return or exacerbation in psychotic symptoms, (b) duration of at least one week, (c) reduction in functioning, (d) increase in risk, (e) change in clinical management, (f) admission to hospital and (g) use of Mental Health Act at 3, 6, and 12-months. A total score of a) to d) will be derived to reflect the impact of the relapse on the service user and also a total score of e) to g) to represent the clinical response. Finally the severity of the relapse will be reported

3.7.3.2 Candidate Secondary Outcomes (at 3, 6 and 12 months unless otherwise stated)

(i) *Mental Health Status:* The Positive and Negative Syndrome Scale (PANSS), Personal and Social Performance Scale (PSP) and the Calgary Depression Scale for Schizophrenia (CDSS) will be completed with service user participants.
(ii) *Substance use measures:* Time Line Follow Back for drugs and alcohol (TLFB).
(iii) *Emotional distress:* Hospital Anxiety and Fear of Recurrence Scale (FoRSe), Hospital Anxiety and Depression Scale (HADS), and the Personal Beliefs about Illness Questionnaire-Revised (PBIQ-R).
(iv) *Service Engagement:* The Service Attachment Scale (SAS) and the Medication Adherence Rating Scale will be completed by service user participants.

3.7.3.3 Candidate Mechanisms (at 3, 6 and 12 months unless otherwise stated)

(i) Recovery and Self Efficacy: Questionnaire for Personal Recovery (QPR; Neil et al., 2009), General Self Efficacy Scale (GSE; Schwarzer & Jerusalem 1995) will be completed by service user participants.

(ii) Social and Interpersonal Context: Psychosis Attachment Measure (PAM; Berry, Wearden, Barrowclough & Liversidge, 2006) and adapted Perceived Criticism Measure (PCM; Dianne, Chambless, Kimberly & Blake, 2009) will be completed by service user participants.

3.7.4 Carer Outcomes

The Involvement Evaluation Questionnaire (IEQ; van Wijngaarden et al., 2000) will be completed as a measure of carers' worrying, tension, urging and supervision. A Carer Perceived Criticism Measure adapted from the PCM described above will be used as a measure of Carers' perspectives on relationship quality.

3.7.5 Care Coordinator Outcomes

Participants care co-ordinators will complete the Service Engagement Scale (SES; Tait et al., 2004).

See Dummy tables in Section 7 for summary descriptions of each variable – Using these and variable plots data shape will be assessed and taken into account within each of analyses

4 Statistical principals

4.1 Confidence intervals

Statistical analysis will be tested at the 2-sided 5% significance level with any estimates displayed with 95% confidence intervals (CIs). The mean, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles, such as median, or minimum and maximum will use the same number of decimal places as the original data. Estimated parameters, not on the same scale as raw observations (e.g. regression coefficients) will be reported to 3 significant figures.

4.2 Adherence and Protocol deviations

As a feasibility study, adherence and deviations will be the main focus. Assessing and understanding these will inform the next phase. It may be possible to use these data and an internal pilot to formulate Stop/Go criteria for the full trial.

4.3 Analysis populations

Statistical analysis will be intention-to-treat based on all subjects within each randomised cluster. Missingness will be one of the feasibility outcomes to investigate. For this phase, complete case analyses will be conducted.

All subjects will be included in our analyses who were consented and received any study treatment (including TAU) post randomisation but we will exclude subjects who drop out prior to their cluster being randomised and thus before they received any treatment or knew what the allocated treatment would be.

5 Trial Population

The trial population will consist of all participants that are assessed to be eligible and provide consent to be followed up.

6 Statistical Analysis

The analysis will follow the guidelines of the CONSORT statement for clustered randomised trials and recommendations for the analysis of clustered randomised trials when presenting and analysing the data. Baseline characteristics of the study population will be summarised separately within each randomised group using means (with standard deviations), medians (with inter-quartile ranges) and numbers (with percentages) where appropriate. Baseline characteristics will also be presented for dropouts and completers within each treatment group. Similarly the primary and secondary outcomes at baseline and all follow-up by treatment groups will be described.

Further analyses will be conducted on all the primary and secondary outcomes. These will be performed on the basis of the intention-to-treat principle and will utilise all available follow-up data from all randomised participants. There will be repeated measures on individual patients. The design was originally nested within care coordinators who are nested within teams (the unit of randomisation) who are nested within region (Australia and UK). However, as a feasibility study there is potential of insufficient degrees of freedom to account for all of these, further reduced by the original matching and the fact that there are small number of clusters. Matching was used as a purposively sampling strategy to ensure a sufficient range of 'service type' and 'geographical location'. However, this is not necessarily the approach for a future main study - provided there were enough clusters then there would be a sufficient range of services and geographies such that standard randomisation without matching would balance these factors between the treatment arms. For this feasibility study analysis models for the primary outcome will use a simplified approach whereby we will analyse the unmatched data, adjusted for baseline information of the outcome where possible, include a fixed effect for country and account for any possible team/service clustering using a random effects robust variance.

The results will be displayed as estimates with 95% confidence intervals (CIs) derived from appropriate generalised linear models (GLM), and 95% CIs around observed differences between treatment arms, appropriately adjusted to accommodate the small number of clusters (Leyrat et. Al., 2018). The time to relapse will be illustrated using graphical representation similar to a survival curve.

All model assumptions will be assessed by means of the summary statistics and/or graphical plots to ensure the correct use of transformations or the most appropriate model for that data type.

6.1 Derived Variables - Patient Reported Outcome Measures (PROMs):

There are several participant reported outcomes collected using validated questionnaires with items combined into an overall score and/or subscales according to validated criteria (See Appendix B for criteria for the PROMS derived for this trial). Codes for these are developed in-house, checked and the code verified using dummy data by an independent statistician.

6.2 Missing Data

Understanding the level and potential type of missingness is an aim of the study and so we will describe missing data.

Provided missingness for any derived scores described in the section 6.1 and Appendix A, is less than 50% (or at a level as specified by the definitive reference for that variable- see Appendix B for information on the scoring for each assessment measure) we will estimate missing data using within-person-mean imputation. This assumes the missingness to be completely at random (MCAR). Any overall total scores will use within domain imputations (provided these are mutually exclusive) whilst maintaining the overall 50% (or otherwise specified) rule. We may also consider simple pattern mixture modelling (i.e. assume best/worst case scenario for missing items). Outcome variables (derived or otherwise) that remain missing will be imputed (Imputing the mean of the within-variable) but only at baseline to ensure that the impact of such missingness does not restrict our model analyses, since each baseline outcome will be adjusted for as a covariate in each outcome model.

6.3 Subgroup Analyses/ Sensitivity Analyses

None pre-specified.

7 Dummy Tables

7.1 Baseline

Table 1: General baseline characteristics - service users

Characteristic	Categories	Empower	TAU
Male missing	n(%)		
Age	n, mean(sd), median(IQR), min/max		
Years Of Education			
Participants live in	n(%)		
UK			
Australia			
Country missing			
UK Ethnic Groups	n(%)		
Scottish;			
Other British;			
Irish;			
Gypsy / Traveller;			
Polish;			
Other white ethnic group;			
M/M ethnic groups;			
Pakistani*			
Indian, *			
Bangladeshi, *			
Chinese, *			
Asian - Other;			
African, *			
African - Other;			
Caribbean, *			
Black, *			
Caribbean or Black - Other;			
+missing			
Born In Australia missing	n(%)		
Aboriginal			
Strait Islander			
Do you have a Carer +missing	n(%)		
Mental health service 1stContact	n, mean(sd), median(IQR), min/max		

* Scottish, British born M/M: mixed or multiple# Only participants living in Australia

Table 2: Baseline Clinical Characteristics (include remission) of service users

Assessment	Summary	Empower	TAU
Remission - at baseline			
1:Full remission;	n(%)		
2:Partial remission;			
3:Non-remission;			
4:Inadequate evidence;			
+missing			
i) Mental health status			
PANNS			
Positive	Pseudo continuous (1-7) n; mean(sd), median(IQR), min/max		
Negative			
Disorganisation			
Excitement			
Emotional Distress			
Total PANNS	Pseudo Cont (30-210) n; mean(sd), median(IQR), min/max		
PSP			
Socially Useful	Pseudo continuous (1-6) n; mean(sd), median(IQR), min/max		
Social Relationships			
Self-Care			
Aggressive Behaviours			
Scale (1-10)	n; mean(sd), median(IQR), min/max		
Score (1-100)			
Calgary			
total score(0-27)	n; mean(sd), median(IQR), min/max		
ii) Substance use			
TLFB:			
Have you had … in past 28 days			
Alcohol	Y n(%)+missing		
Cannabis			
Drugs			
How many days were you ….			
Drinking Alcohol	n, mean(sd), median(IQR), min/max		
Heavy Drinking			
Cannabis taking			
Taking Another Main Drug			
iii) Emotional distress			
HADS Scales			
Anxiety total	N; mean(sd) Median(iqr)		
Depression total			

	Min/max		
PBIQ-R Domains			
Control over illness	N; mean(sd) Median(iqr) Min/max		
Shame			
Entrapment			
Loss			
Social Marginalisation			
iv) Service engagement			
SAS Domains			
Listening	N; mean(sd) Median(iqr) Min/max**?**		
Consistency			
Ending			
Safety			
Talking			
Comfort			
SAS total			
MARS Score (0-10)	N; mean(sd) Median(iqr) Min/max**?**		

Table 3: Baseline Mechanism characteristics – service users

Assessment	**Summary statistics**	**Empower**	**TAU**
i) Recovery and Self Efficacy:			
QPR Score (0-60)	n, mean(sd), median(IQR), min/max		
GSE score (10-40) :	n, mean(sd), median(IQR), min/max		
ii) Social and Interpersonal Context:			
PAM Domains			
Attachment Avoidance	n, mean(sd), median(IQR), min/max		
Attachment Anxiety			
PCS Perceived Criticism and Warmth Measure Pseudo Cont (1-10)			
How critical do you think you are of [person]?	n; mean(sd), median(IQR), min/max		
How critical do you think [person] is of you?			
How warm are you towards [person]?			
How warm is [person] towards you?			
How supported do you feel by [person]?			

Table 4: Carers - Baseline *Demographics*

Characteristics	Summary	Empower	TAU
Male	n(%)		
Age	n, mean(sd), median(IQR), min/max		
Main Occupation n(%)			
Employed full-time	n(%)		
Employed part-time			
Casual employment			
Unemployed			
Student full-time			
Student part-time			
Volunteer			
Retired			
Home duties			
Education			
Years Of Education			
Living in:			
UK	n(%)		
Australia			
Missing			
UK Ethnic Groups			
1. Scottish;	n(%)		
2. Other British;			
3. Irish;			
4. Gypsy / Traveller;			
5. Polish;			
6. Other white ethnic group;			
7. M/M ethnic groups;			
8. Pakistani*			
9. Indian, *			
10. Bangladeshi, *			
11. Chinese, *			
12. Asian - Other;			
13. African, *			
14. African - Other;			
15. Caribbean, *			
16. Black, *			
17. Caribbean or Black - Other;			
18. +missing			
Born In Australia	n(%)		
Aboriginal	n(%)		
Strait Islander	n(%)		

*Scottish, British born M/M:mixed or multiple **#**Only participants living in Australia

Table 5: Co-ordinators- Baseline characteristics

Characteristics	Summary	Empower	TAU
Male Missing	n(%)		
Age	n, mean(sd), median(IQR), min/max		
Length of time with current team	n, mean(sd), median(IQR), min/max		
Length of time since qualified	n, mean(sd), median(IQR), min/max		

7.2 Feasibility and acceptability Measures

Table 6: Acceptability / Usability at 3, 6 and 12 months (EMPOWER service users only)

Item	Category	Summary	Empower 3m	6m	12m
App rating -					
1. Roughly how often do you use the App?	1- not at all To 5- daily	median (iqr)			
2. Roughly how often do you share information from the App (e.g. charts) with your keyworker?	0:Not sure; n(%) 1:Not at all; to 4:Often	Not sure; n(%) + rest as median (iqr)			
3. Roughly how often do you share information from the App (e.g. charts) with your family member/carer?		Not sure; n(%) + rest as median (iqr)			
4. Roughly how often have you accessed charts on EMPOWER?		Not sure; n(%) + rest as median (iqr)			
UMars					
1. Is the app interesting to use?	1 – not interesting To 5 very interesting	median (iqr)			
2. How easy is it to learn how to use the app; how clear are the menu labels, icons and instructions?	1 - Not to 4 easy to learn	median (iqr)			
3. Does moving between screens make sense; does app have all necessary links between screens?	1. Not logical To 5 Perfectly logical,	median (iqr)			
4. Is app content (including messages) correct, well written, and relevant to the goal/topic of the app?	1. Irrelevant to 5-Highly relevant,	median (iqr)			
5. Does the information within the app (including messages) seem to come from a credible source?	1-Suspicious source; To 5 legitimate source;	median (iqr)			
6. Would you recommend the	1- [Not at all]	median (iqr)			

EMPOWER app to people who might benefit from it?	To 5- Definitely				
7. What is your overall star rating of the app? 98:NA This is the first App Ive used so I cant fully judge;	1: worst apps I've used; to 5: best	median (iqr)			
8. This app has increased my awareness of the importance of monitoring my mental health and wellbeing	1 - Strongly disagree; to 5 - Strongly agree;	median (iqr)			
9. This app has increased my knowledge/understanding of my mental health and wellbeing		median (iqr)			
10. The app has changed my attitudes toward improving my mental health and wellbeing		median (iqr)			
11. The app has increased my intentions/motivation to support my mental health and wellbeing		median (iqr)			
12. This app would encourage me to seek further help for my mental health and wellbeing (if I needed it		median (iqr)			

Table 7: Feasibility Outcomes for service users at baseline, 3, 6 and 12 months

Assessment	Summary statistics	Empower				TAU			
		Base	3m	6m	12m	Base	3m	6m	12m
1. Do you use health and wellbeing Apps?	n(%) 0:Not sure; 1:Yes; 2:No								
2. Roughly how often do you use health and wellbeing Apps?	0:Not sure; as n(%) 1:Not at all; to 4:Often; Summarised as median (iqr)								
3. In the last three months how often have you sought help in relation to your EWS?									
4. In the last three months how often has your family member or a carer sought help on your behalf in relation to your EWS?									
5. How often has this resulted in a change in your clinical care e.g. appointment brought forward, changes in medication, referral to crisis team?									

Table 8: Feasibility Outcomes for carers at baseline, 3, 6 and 12 months

Assessment	Summary statistics	Empower				TAU			
		Base	3m	6m	12m	Base	3m	6m	12m
1. In the last 3 months how often has [person cared for] discussed their early warning signs with you?	All scores 0:Not sure; 1:Not at all; 2:Rarely; 3:Sometimes; 4:Often; 98:N/A q1 only Summarised as median (iqr)								
2. In the last 3 months how often times has [person cared for] sought help in relation to their EWS?									
3. In the last 3 months how often have you sought help on their behalf in relation to early warning signs?									
4. In the last 3 months how often has this resulted in a change in clinical management, e.g. appointment brought forward, changes in medication, referral to crisis team.									

Table 9: Feasibility Outcomes for co-ordinators at baseline, 3, 6 and 12 months

item	n(%)	Empower				TAU			
		Base	3m	6m	12m	Base	3m	6m	12m
1. In the last 3mo how often has [person in the study] discussed their EWS with you?	All scores 0:Not sure; 1:Not at all; 2:Rarely; 3:Sometimes; 4:Often; 98:N/A q1 only Summarised as median (iqr)								
2. In the last 3 mo how often times has [person in the study] sought help in relation to their EWS?									
3. In the last 3mo how often has their family member or a carer sought help on their behalf in relation to EWS?									
4. In the last 3mo how often has this resulted in a change in clinical management, e.g. appointment brought forward, changes in medication, referral to crisis team									

7.3 Primary Outcome – analysis

All model estimates are as a result of adjustment as specified in the Statistical Analysis Section 7

Table 10: Primary outcome analysis

	Empower		TAU		Estimate	95% CI
Relapse over the 12 month follow up	n/N	%	n/N	%		
By 12months **y/n**					ARD=xxx	
By 12months **y/n**					RR=xxx	
Time to first relapse	Mean(sd) Median(iqr) min, max		Mean(sd) Median(iqr) min, max		HR=xxx	

Adjusted for a fixed country effect and possible team/service clustering using a random effects robust variance.

ARD: absolute risk difference; **RR:** relative risk; **HR:** hazard ratio

Figure 1 Relapse Free over time -***see below for example not directly this study***

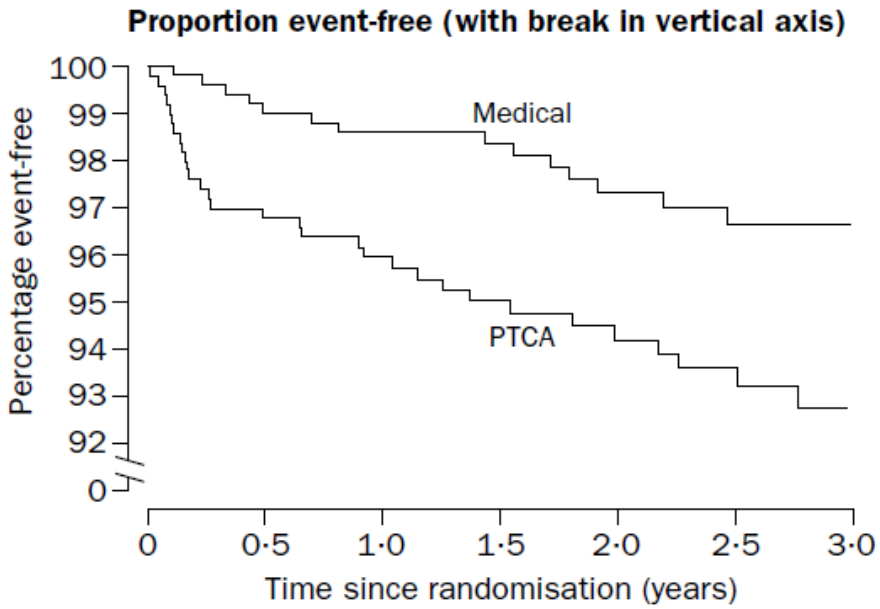


Table 11: Relapse characteristics at 3, 6 and 12 months

	Empower			TAU		
Item	**3 mo**	**6 mo**	**12 mo**	**3 mo**	**6 mo**	**12 mo**
Characteristics of Relapse n/N (%)						
a) return or exacerbation in psychotic symptoms						
b) duration of relapse						
c) reduction in functioning						
d) increase in risk						
Total Service user a-d						
e) change in clinical management						
f) admission to hospital						
g) use of Mental Health Act						
Total Clinical Response e-g						
Type of relapse n/N (%)						
I						
II						
III						
Number of relapses:						
Mean(sd) Median(iqr) min, max)						

Table 12: Severity Assessment for each 'relapse event' over 12 months

Relapse Severity Score (1-7)	**Summary**	**Empower**	**TAU**
Score associated with each relapse event over the 12 month follow-up period	n:n_e: Mean(sd) Median(iqr) min, max		

n: represents the number of patients effected; **n_e**: represents the number of events

Adverse events and Device deficiencies - to be summarised by PTM – To be *verified by statistics*

Table 13: Summary of Adverse Events

Variable	**Empower**	**TAU**	**All**
Total Number of AEs			
People			
Male			
Female			
SAEs			
Anticipated events			
Yes			
No			
Related to:			
Device			
App			
Procedure			
Intensity of the Events			
Mild			
Mod			
Severe			

Table 14: Fear of Recurrence Scale (FoRSe) at baseline, 3, 6 and 12 months

Assessment	Estimate	Empower	TAU	Effect size	95% CI
FoRSE Domains					
Intrusiveness	n; mean(sd) Median(iqr) Min/max				
Baseline					
3 months					
6 months					
12months					
Awareness					
Baseline					
3 months					
6 months					
12months					
Relapse					
Baseline					
3 months					
6 months					
12months					
FoRSE Total					
Baseline					
3 months					
6 months					
12months					

7.4 Secondary Measures at baseline and Outcomes

Table 15: Secondary Clinical (Subscales and Total Scores) outcomes at baseline, 3, 6 and 12 months

Assessment	Estimate	Empower	TAU	Effect size	95% CI
i) Mental health status					
PANNS					
Positive					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Negative					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Disorganisation					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Exciement					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Emotional Distress					
Baseline					
3 months	n, mean(sd) median(IQR) min/max				
6 months					
12months					
Total					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
PSP					
Socially useful	(1-6)				
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Social relationships	(1-6)				
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Self Care	(1-6)				
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
PSP scale	(1-10)				
Baseline					

3 months	n, mean(sd) median(IQR) min/max				
6 months					
12months					
PSP score (1-100)					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Calgary total	Pseudo Cont (0-				
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					

ii) Substance use

TLFB: … in past 28 days						
Have you had …	**Empower n/N (%)**	**TAU n/N (%)**	**ARD**	**95% CI**	***RR***	**95% CI**
Alcohol						
Baseline						
3 months						
6 months						
12months						
Cannabis						
Baseline						
3 months						
6 months						
12months						
Drugs						
Baseline						
3 months						
6 months						
12months						

How many days were you …	**Estimate**	**Empower**	**TAU**	**Effect size**	**95% CI**
Drinking Alcohol	N; mean(sd) Median(iqr) Min/max				
Baseline					
3 months					
6 months					
12months					
Heavy Drinking					
Baseline					
3 months					
6 months					
12months					
Cannabis taking					
Baseline					
3 months					
6 months					
12months					
Taking Another Main Drug					
Baseline					
3 months					
6 months					

12months					
iii) Emotional distress					
Assessment	**Estimate**	**Empower**	**TAU**	**Effect size**	**95% CI**
HADS Scales					
Anxiety total					
Baseline	N; mean(sd) Median(iqr) Min/max				
3 months					
6 months					
12months					
Depression total					
Baseline					
3 months					
6 months					
12months					
PBIQ-R Domains					
Control over illness					
Baseline	N; mean(sd) Median(iqr) Min/max				
3 months					
6 months					
12months					
Shame					
Baseline					
3 months					
6 months					
12months					
Entrapment					
Baseline					
3 months					
6 months					
12months					
Loss					
Baseline					
3 months					
6 months					
12months					
Social Marginalisation					
Baseline					
3 months					
6 months					
12months					
iv) Service engagement					
SAS Domains					
Listening					
Baseline					
3 months					
6 months					
12months					

Consistency	N; mean(sd) Median(iqr) Min/max**?**				
Baseline					
3 months					
6 months					
12months					
Ending					
Baseline					
3 months					
6 months					
12months					
Safety					
Baseline					
3 months					
6 months					
12months					
Talking	N; mean(sd) Median(iqr) Min/max**?**				
Baseline					
3 months					
6 months					
12months					
Comfort					
Baseline					
3 months					
6 months					
12months					
SAS Total					
Baseline					
3 months					
6 months					
12months					
Mars Score (0-10)					
Baseline	N; mean(sd) Median(iqr) Min/max**?**				
3 months					
6 months					
12months					

Table 16: Models for Mechanism outcomes (Subscale and Total Scores) at baseline, 3, 6 and 12 months

Assessment	Estimate	Empower	TAU	Effect size	95% CI
i) Recovery and Self Efficacy:					
Questionnaire for Personal Recovery (QPR) Score 0-60					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
General Self Efficacy Scale GSE score (10-40) :					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
ii) Social and Interpersonal Context:					
Assessment	**Estimate**	**Empower**	**TAU**	Effect size	95% CI
Psychosis Attachment Measure (PAM)					
Attachment Avoidance					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Attachment Anxiety					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Perceived Criticism Scale (PCS) (0-10)					
How critical do you think you are of [person]?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
How critical do you think [person] is of you?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
How warm are you towards [person] you?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
How warm is [person] towards you?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					

How supported do you feel by [person]?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					

Table 17: Carer outcomes (Subscale and Total Scores) at baseline, 3, 6, and 12 months

Assessment	Estimate	Empower	TAU	Effect size	95% CI
IEQ Domains					
Tension					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Supervision					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Worrying					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Urging					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Total					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
PCS					
1. How critical do you think you are of [person]?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
2. How critical do you think [person] is of you?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
3. How warm are you towards [person]?					
Baseline	n, mean(sd) median(IQR)				
3 months					

6 months	min/max				
12months					
4. How warm is [person] towards you?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
5. How supported do you feel by [person]?					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					

Table 18: Care coordinator (Subscale and Total Scores) outcomes at basline, 3, 6 and 12-months

Assessment	Estimate	Empower	TAU	Effect size	95% CI
SES Domain Scores higher scores indicate lower engagement.					
Availability					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Collaboration					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Help Seeking					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Treatment Adherence					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					
Total (0-42)					
Baseline	n, mean(sd) median(IQR) min/max				
3 months					
6 months					
12months					

8 References

Cluster randomized trials with a small number of clusters: which analyses should be used? Clémence Leyrat Katy E Morgan Baptiste Leurent Brennan C Kahan. International Journal of Epidemiology, Volume 47, Issue 1, February 2018, Pages 321–331, https://doi.org/10.1093/ije/dyx169

9 Appendices: *see separate documents*

9.1 A: References and details of Sub-scales and Scores

9.2 B: Tables for item level data per measure at each time point including baseline