Group acceptance and commitment therapy (ACT) for patients and caregivers in psychosis services: feasibility of training and a preliminary randomised controlled evaluation.

Suzanne Jolley; Louise C Johns (joint first authors); Emma O'Donoghue; Joseph Oliver; Mizanur Khondoker; Majella Byrne; Lucy Butler; Carmine De Rosa; Daniela Leal; Jessica McGovern; Brigita Rasiukeviciute; Faye Sim; Eric Morris

Title: Group acceptance and commitment therapy (ACT) for patients and caregivers in psychosis services: feasibility of training and a preliminary randomised controlled evaluation. (Running title: ACT for Recovery)

Authors: Suzanne Jolley[a], Louise C Johns[a,b] (joint first authors), Emma O'Donoghue[a,c], Joseph Oliver[d], Mizanur Khondoker[e], Majella Byrne[a,c], Lucy Butler[a], Carmine De Rosa[c], Daniela Leal[c], Jessica McGovern[a,c], Rasiukeviciute, Brigita[a], Faye Sim[c], and Eric Morris[f].

Author affiliations:

[a]King's College London, Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, London, UK

[b]Department of Psychiatry, University of Oxford, UK

[c]South London and Maudsley NHS Foundation Trust, London, UK

[d]University College London, London, UK

[e]Norwich Medical School, University of East Anglia, Norwich, UK.

[f]School of Psychology and Public Health, La Trobe University, Melbourne, Australia

Corresponding author: Dr. Suzanne Jolley, PO77 Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, King's College London, 16, De Crespigny Park, Denmark Hill, London, SE5 8AF, UK. Tel: +44 (0)2078485028; Fax +44 (0)2078485006. Email: suzanne.jolley@kcl.ac.uk. https://orcid.org/0000-0003-1622-0051

Acknowledgements: We thank all participating service-users, caregivers, and community staff. We gratefully acknowledge financial support from the Maudsley Charity (ref. 764).

Role of the funding source: Sponsors were independent of the design of the study, the collection, analysis and interpretation of data, the writing of the report, and the decision to submit the paper for publication. The corresponding author confirms that she had full access to all the data for the study, and final responsibility for the decision to submit the report, in this form, for publication.

Data availability: We do not have consent to make this clinical data publicly available, but the data is available from the lead author upon reasonable request (i.e. concordant with conditions of consent).

Disclosure statement: LJ, EO'D, JO and EM provide training in ACT. JO and EM have chaired the British Association of Behavioural and Cognitive Psychotherapy ACT Special Interest Group. JO runs an independent ACT consultancy. There are no other conflicts of interest.

Abstract (248 words)

Objective: Psychological interventions reduce the impact of psychosis, but widescale implementation is problematic. We tested the feasibility of group Acceptance and Commitment Therapy for psychosis (G-ACTp), delivered by frontline staff and co-facilitated by service-user experts-by-experience (SU-EbyE), for service-users and informal caregivers (ISRCTN: 68540929). We estimated recruitment/retention rates and outcome variability for future evaluation.

Method: Staff and SU-EbyE facilitators completed one-day workshops then delivered closely-supervised G-ACTp, comprising four sessions (weeks 1-4) and two boosters (10-weeks and 12-weeks). Participants recruited from adult community psychosis services were randomised to receive G-ACTp immediately or after 12-weeks, completing outcome assessments at 0-weeks, 4-weeks, and 12-weeks. Service-use/month was calculated for 1-year pre-randomisation, weeks 0-12, and 5-year uncontrolled follow-up.

Results: Of 41 facilitators trained (29 staff, 12 SU-EbyE), 29 (71%; 17 staff, 12 SU-EbyE) delivered 18 G-ACTp courses. Participant refusal rates were low (9% of service-users [10/112]; 5% of caregivers [4/79]); 60% of those invited to participate attended ≥1 G-ACTp session (64% of service-users [39/61]; 56% of caregivers [35/63]). Randomisation of facilitators and participants proved problematic and participant follow-up was incomplete (78% [66/85]; 82% of service-users [36/44]; 73% of caregivers [30/41]). Effect sizes ranged from very small to large mostly favouring treatment. Service-use reductions require cautious interpretation, as very few participants incurred costs.

Conclusions: Implementation appears feasible for service-users; for caregivers, retention needs improving. Outcome variability indicated n=100-300/arm followed-up (α=0.05, 90% power). Methodological limitations mean replication is needed: identified sources of potential bias may be reduced in a cluster randomised design with sessional outcome completion.

Keywords: schizophrenia; cognitive therapy; community mental health services; group psychotherapy

Abbreviations: NICE: National Institute for Health and Care Excellence; ACT: Acceptance and Commitment Therapy; G-ACTp: ACT groups for people with psychosis; BME: Black and Minority Ethnic

Text: 4937 words

Introduction

Psychosis is societally and personally costly, reducing quality of life, social inclusion and employment opportunities, for both service-users and informal caregivers (United Kingdom National Institute for Health and Care Excellence (UK NICE), 2014; Chong et al., 2016). Psychological interventions, for service-users and for caregivers, now form recommended routine care in international healthcare guidelines (NICE, 2014, Dixon et al., 2010). Service-user interventions target persisting positive psychotic symptoms, emotional problems, and negative symptoms, with small to medium average treatment effects (NICE, 2014; Jauhar et al., 2018). For caregivers, unhelpful appraisals, perceived burden of care, social isolation, and avoidant coping drive emotional distress and, via problematic interactions with service-users, service-user relapse (Kuipers, Onwumere, & Bebbington, 2010). Interventions targeting these maintaining factors improve caregiver wellbeing and caregiving relationships, reducing relapse and readmission (NICE, 2014). However, the complexity of therapies, and the consequent training and supervision burden, has precluded effective dissemination, especially to frontline and peer workers, restricting delivery and opportunities to fully embrace recovery and coproduction principles (Ince, Haddock, & Tai, 2015; The Schizophrenia Commission, 2012; Thomas, 2015; Carr et al., 2016; Guhne et al., 2020).

Acceptance and Commitment Therapy (ACT) is a process-oriented, contextual cognitive behavioural approach, aiming to improve wellbeing, functioning, and quality of life by increasing psychological flexibility and reducing unhelpful self-regulation (e.g. worry, rumination, suppression, avoidance; Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Hayes, Strosahl, & Wilson, 2012). Psychological flexibility, characterised by acceptance, mindful

awareness, choice, and values-based actions, is associated with improved wellbeing and quality of life in clinical and non-clinical contexts, including for people with psychosis and psychosis caregivers (Kashdan and Rottenberg, 2010; Gloster et al., 2017; Goldstone et al, 2012; Morris, Garety & Peters, 2014; Udachina et al., 2014; Valiente et al., 2015; Varese et al., 2016; Castilho et al., 2017; Jansen et al., 2017; 2019). Interventions promoting psychological flexibility are potentially helpful for many disorders (A-Tjak, Davis, Morina, Powers, Smits, & Emmelkamp, 2015) including psychosis, improving symptoms, functioning, and service use, with indications of change through targeted mechanisms, and positive effects at follow-up, although findings are mixed and more rigorously controlled studies are needed (Ost, 2014; Khoury, Lecomte, Gaudiano, & Paquin, 2013; Cramer, Lauche, Haller, Langhorst, & Dobos, 2016; Louise et al., 2018; Bach, Hayes, & Gallop, 2012). Emerging evidence also suggests applicability to caregivers in cancer, dementia, chronic pain and end-of-life caring contexts (Davis, Deane, & Lyons, 2015; Toussaint, Barry, Bornfriend, & Markman, 2014; Losada et al., 2015; Wallace et al, 2016; Kishita et al., 2018), raising the possibility of extending ACT approaches to support caregivers of people with psychosis, in line with NICE (2014) recommendations.

Importantly for implementation, brief courses of group ACT for psychosis (G-ACTp), comprising four sessions each of two hours, have shown promise in service evaluations and uncontrolled studies, improving pre-post outcomes for people with psychosis, suggesting potential for cost-effective, widescale provision (Morris et al., 2013; Johns et al., 2015; Butler et al., 2016; O'Donoghue et al., 2018). However, outcomes have yet to be evaluated in a randomised controlled trial (RCT) and the feasibility of frontline, recovery-focused delivery is unknown.

Aims of the study

We set out to evaluate the feasibility of providing brief courses of G-ACTp for service-users and caregivers in community psychosis services, and to estimate recruitment, retention, and variability in effect sizes and outcomes (to inform sample size for future evaluation) using a pragmatic randomised controlled design (ACT for Recovery, ISRCTN: 68540929). G-ACTp was designed to be delivered, following training, by frontline staff, co-facilitated by service-users with lived experience of mental health services (service-user experts by experience, SU-EbyE). Feasibility outcomes assessed potential for successful delivery and evaluation, operationalised as: 1) staff/SU-EbyE trained to competently deliver/co-facilitate (target: 16 staff; 16 SU-EbyE); 2) participant recruitment to target (48 service-users; 48 caregivers); 3) intervention uptake exceeding current service-based estimates >50%; 4) retention ≥ 80%. Implementation and service-use outcomes were followed up over five years.

Material and methods

Study design

We conducted a pragmatic randomised controlled feasibility trial of G-ACTp for service users and caregivers in community psychosis services, evaluating a model of delivery by trained frontline staff and SU-EbyE. Participants were randomised in a 1:1 ratio to one of two arms, receiving G-ACTp either immediately (ACTnow) or after 12-weeks (ACTlater). Randomisation was carried out by a registered UK Clinical Trials Unit, employing blocks of randomly varying size, and was stratified by service-user or caregiver status. We measured outcomes at baseline (0-weeks), post-intervention (4-weeks), and post-booster (12-weeks).

Proposed primary common outcomes of mental wellbeing and distress were also followed up (uncontrolled) at 6-months. Secondary common outcomes were functioning (interference/activity/health-related quality of life) and process (acceptance, values, mindfulness). Secondary service-user only outcomes were psychotic symptoms, recovery, and service use. Service use and implementation outcomes were followed up (uncontrolled) over five years.

Training

1) Training participants

Training was advertised during December 2012 within the host organisation (a large UK National Health Service mental health Trust) to frontline staff in recovery services (n≈160) and user involvement networks. Those expressing interest were briefed before committing to participate; no selection criteria were applied. Staff participated during usual working hours, without additional payment. SU-EbyEs were paid for all involvement (training, delivery, supervision).

2) Training procedure

Staff/SU-EbyEs attended a 6-7 hour one-day workshop and delivered/co-facilitated a G-ACTp course with a competent lead therapist (EM, LJ, JO, EO'D). Leads held sessional pre-group (planning and practising) and post-group (reflection and adherence rating) supervision. Leads also monitored adherence to protocol, rating ACT-consistent therapist behaviours (Morris, 2013), and ensured ACT-consistency off-manual (e.g. responses to participant

comments/questions). Leads attended weekly peer supervision and held separate supervision groups for staff/SU-EbyEs (O'Donoghue et al., 2018).

3) Training evaluation

Planned randomisation of facilitators (training immediately/after 12-weeks) proved infeasible due to facilitators' diary commitments and job plans. Workshop training was therefore evaluated pre-post using the ACT Knowledge Questionnaire (AKQ, Luoma and Vilardaga, 2013) comprising 16 yes/no rated items, scored 1 or 0 respectively, generating a total score from 0 (poor knowledge) to 16 (excellent knowledge). Previous research reports increased mean scores from 5.8 to 8.5 following ACT workshops, with medium effect sizes (Richards et al., 2011). Post-training competence to deliver/co-facilitate was judged by lead therapists, based on observation during groups and supervision, using sessional ACT adherence ratings (Morris, 2013). Whether facilitators delivered G-ACTp routinely (i.e. outside the study) after training was recorded at 20-weeks and 5-year follow-up (5-year-FU).

Service-user/caregiver participants

Recruitment/randomisation occurred between January 2013 and March 2014 in community psychosis services. Outcomes were collected by March 2015; service-use and implementation data by May 2019. Service-user inclusion criteria matched the service: adults (18-years+) with psychosis (according to the treating team, an established diagnosis or current, persistent, distressing/disabling positive, negative, or disorganised psychotic symptoms in the context of any condition). Caregivers were adults, living with and/or informally caring for a service-user. Exclusion criteria were: insufficient English to understand assessment/therapy materials; clinical presentation precluding participation in therapy (e.g. being highly

aroused). Clinical teams identified both service-users and caregivers meeting study criteria from their current caseloads. Contact was attempted for all referrals with usable contact information. There was no requirement for service-users to have a caregiver participating in the study, or vice versa. The CONSORT diagram is shown in Figure 1.

Demographics and outcome measures

The outcome completion schedule is included in Appendix I.

1) Demographics

Age (in years), gender, ethnicity, and caregiving relationship (caregivers only) was collected by self-report supplemented by the medical record. Ethnicity was dichotomised into Black and Minority Ethnic (BME) or White European/American (non-BME). Diagnoses, according to the treating team, were grouped into schizophrenia-spectrum; bipolar affective disorder; and any other affective/behavioural disorder with psychotic symptoms (Table 1).

2) Proposed primary outcomes

Positive wellbeing (Warwick-Edinburgh Mental Wellbeing Scale, WEMWBS, Tennant et al., 2007)

WEMWBS comprises 14 items self-rated from one (‘none of the time’, lower wellbeing) to five (‘all of the time’, higher wellbeing), totalling 14-70. Internal consistency, test-retest reliability, content, and criterion validity are good: psychosis-specific studies suggest lower wellbeing (Mean: 42.2, standard deviation, SD 12.9, Jolley et al., 2015; Mean: 39.1 SD 11.6,

Broyd et al., 2016) than population norms (50.7, 95% confidence interval (CI) 50.3 to 51.1; Tennant et al., 2007; Stewart-Brown & Janmohamed, 2008).

Distress (Clinical Outcomes in Routine Evaluation, CORE-10, Barkham et al., 2013)

CORE indexes global distress across ten self-rated items, totalling 0 (low) to 40 (high). Psychometrics are robust: psychosis-specific means (16.0, SD 8.9, Jolley et al., 2015) show greater distress than general population scores (4.7, SD 4.8); scores >11 indicate clinical distress (Connell and Barkham, 2007).

3) Secondary outcomes

Functioning measures

Self-rated impairment from 0 (low) to 10 (high) across domains of work/study; social life/leisure activities; and family life/home responsibilities forms the Sheehan Disability Scales (SDS, Sheehan, 1983) rating total Interference from 0-30. Construct validity, internal reliability and sensitivity to change are good (Sheehan and Sheehan, 2008; Leon et al., 1997). The Time Budget Measure (TBM, Jolley et al. 2005; 2006) assesses, through semi-structured interview, typical weekly activity, rated 0 (doing nothing) to 4 (filled with demanding and complex activity) across four periods/day (morning, lunchtime, afternoon, evening; total 0-112). Validity and reliability are good (Jolley et al., 2005). The EQ5D (Euroqol Group, 1990) assesses Health-related Quality of Life over five questions rating problems with mobility, self-care, activity, pain, and negative emotions, and a 'health thermometer' rating current health from 0 (poor) to 100 (good), and is valid and reliable for psychosis populations (Barton et al., 2009).

Process measures

The Acceptance and Action Questionnaire (AAQ-II, Bond et al., 2011) measures psychological flexibility over seven items rated 1 (never true) to 7 (always true); lower scores (range 7-49) indicate greater flexibility. The Valuing Questionnaire (VQ8; Smout et al., 2014) comprises eight items rated 0-6 measuring obstacles to (Obstruction) and engagement in (Progress) values-based actions. The Southampton Mindfulness Questionnaire (SMQ, Chadwick et al., 2008) assesses mindful responding over 16 items rated 0 (strongly disagree) to 6 (strongly agree); totals range from 0 (not mindful) to 96 (very mindful). Psychometric properties for each scale are reported by the authors and are acceptable.

Service-user only measures

Psychotic Symptoms Rating Scale (PSYRATS, Haddock et al., 1999)

Hallucinations (11 items, total 0-44) and delusions (6 items, total 0-24) are self-rated from 0 (no problem) to 4 (maximum severity) through semi-structured interview; inter-rater reliability is high ($r=0.90$, $p<0.001$; Haddock et al., 1999).

Questionnaire about the Process of Recovery (QPR, Neil et al., 2009)

Twenty-two items generated from personal accounts of recovery, co-designed with service users, are rated from 0 (strongly disagree) to 4 (strongly agree) across two subscales: intrapersonal recovery tasks and interpersonal recovery facilitators. Higher scores (total 0-88) indicate greater recovery; internal consistency ($r=0.47$) and test-retest reliability (intrapersonal subscale $r=0.874$, $p=0.001$; interpersonal subscale $r=0.769$, $p=0.001$) are good (Neil et al., 2009).

Economic outcomes

Service use was calculated from medical records, blind to allocation, by counting emergency department (ED) attendances, and the frequency and duration in days of crisis team or psychiatric inpatient periods of care. Monthly averages were calculated for the year pre-randomisation, 12-weeks pre- and post-randomisation, and (uncontrolled) at 5-year-FU. Treatments costs/participant comprised sessional input of staff, SU-EbyE, and leads, including supervision, for each G-ACTp course, divided by the average number of participants/group. Savings were indicated by reduced costs for ACTnow from 12-weeks pre- to post-randomisation including treatment costs, compared to ACTlater. Costs were calculated using the Personal Social Services Research Unit costs of health and social care (PSSRU, Curtis & Burns, 2016; 2018) and NHS reference costs (Department of Health, 2011; 2016).

Acceptability

Service-users and caregivers completed post-treatment satisfaction ratings (see Table 6, adapted from Attkisson and Zwick, 1982), at 4-weeks, including written feedback on participation, recovery (for service-users) and caregiving relationship changes (for caregivers).

Intervention

A G-ACTp course comprised four sessions, each lasting two hours, delivered weekly, and two further 'booster' sessions at 10-weeks and 12-weeks. The total duration of the intervention was therefore 6 sessions (12 hours), delivered over 12 weeks. Groups followed a

scripted protocol (Butler et al., 2016; Johns et al., 2015; O'Donoghue et al., 2018) employing the 'passengers on the bus' metaphor. Intervention focused on trying new skills, using values, mindfulness, and cognitive defusion exercises, promoting acceptance and highlighting active engagement in ongoing behavioural choices. Service-user and caregiver courses ran separately, differing only in i) the focus of psychological distress in an acted first-person video (psychosis/psychosis caregiving respectively); and ii) a caregiver metaphor of a 'reservoir', needing replenishment to facilitate ongoing caring. Usual care continued irrespective of allocation, without interference, comprising medication, care co-ordination, support with social care, vocational and psychological needs and routine caregiver support. Waitlist participants were offered G-ACTp after completing 12-week assessments.

Procedure

Participants completed self-report baseline measures with a trained research worker, at their own pace, usually in one meeting. Randomisation initially occurred post-baseline, but difficulty contacting participants regarding allocation delayed early groups, disrupting other participants, room-bookings and facilitator schedules. Randomising post-consent, and informing participants immediately post-baseline, improved throughput. However, eleven randomisations remained unrealised through baseline non-attendance following consent. Eight participants were invited unrandomised by the research team to ensure viable group numbers; seven of these were randomised in error post-intervention: all eight were excluded. Adherence to randomised allocation was also problematic. Due to participant travel plans and other commitments, eight ACTlater participants (three service-users, five caregivers) attended ACTnow, so were excluded. Three ACTnow participants (two service-users, one caregiver) attended after the 12-week follow-up; wellbeing/distress was re-assessed prior to

intervention, and these participants were included. The study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki, 2013). All participants gave written informed consent. Ethical approval was obtained from a UK NHS Research Ethics Committee (London-Camberwell St. Giles UK NHS Research Ethics Committee ref. 12/LO/1789); the trial was registered prior to recruitment of the first participant (ISRCTN: 68540929). The study protocol was not published, but was specified in the funding application, which has been submitted with this manuscript for peer review and can be obtained on request from the authors. The CONSORT checklist is included in Appendix II.

Sample size

Recommendations for feasibility pilot studies vary from a sample of at least twelve per group, to a total of 150 (Julious, 2005; Sim & Lewis, 2012; Whitehead et al. 2015; Bell et al., 2018; Albers & Lakens, 2018). We aimed to recruit 96 participants (48 service-users, 48 caregivers), giving 24 per allocation group to estimate recruitment/retention rates, and allowing for loss to follow-up for sample size estimation.

Data analysis

Missing data

Of the 85 participants completing baseline and successfully randomised 66 (78%) completed at least one follow-up, and were included in outcome analyses (Figure 1). Reasons for missing data were: ACTlater participants completing ACTnow (n=8, 3 service-users, 5

caregivers); withdrawal by the study team as too unwell to continue[1] (n=1: ACTnow service-user); data corruption (n=1: ACTlater caregiver; no date/timepoint labelling, rendering data checking impossible); and loss to contact (n=9: 5 ACTnow (1 service-user, 4 caregivers); 4 ACTlater).

Loss to follow-up and missing data were handled under the missing at random (MAR) assumption, whereby predictors of missingness were identified using a series of random intercept logistic regression analyses (White et al., 2011; Stata version 15, Statacorp, 2017) and adjusted for in the analysis model. We investigated age, gender, ethnicity, service-user/caregiver status, wellbeing/distress scores at baseline, Time (0, 4 or 12 weeks), Measure (wellbeing/distress) and Allocation (ACTnow/ACTlater) as potential predictors of missing data. Significant predictors were Allocation (coeff.=-2.7, z=-2.7, p=0.006, 95% CI: -4.6 to -0.8); Time (coeff.=1.2, z=4.3; p<0.001; 95% CI: 0.6 to 1.7); and baseline distress, such that the likelihood of missing data was increased for waitlist participants, post-baseline assessments, and lower distress, but not by any other variable (|z| scores $\leq$ 1.5, p values all > 0.1). Variables predicting missing data were included in the linear mixed model employed to estimate treatment effects for wellbeing/distress, with outcomes at 4-weeks and 12-weeks as repeated measures, covarying for baseline wellbeing and distress, Measure (wellbeing/distress), Time (4 weeks, coded 0 and 12 weeks, coded 1), Status (service-user/caregiver), and an Intervention x Time interaction term, with random clustering effects for treatment group (1-18) and individual. Effect sizes (ES) were calculated as difference in group mean scores from baseline to 4-weeks and 12-weeks (12-weeks pre- and post-

[1] This participant disrupted their group (ate, walked around, entered left the room repeatedly). They had attempted, but only very partially completed baseline measures. Their mental state did not improve sufficiently during the trial to make further participation possible; their economic data were included.

randomisation for service use), divided by the pooled standard deviation (SD), assuming a 0.5 correlation. Training data were analysed using paired t-tests.

Results

Feasibility criteria

1) Staff/SU-EbyE trained to competently deliver/co-facilitate (target: 16 staff; 16 SU-EbyE): partially met

The overall staff/SU-EbyE recruitment target of n=32 was exceeded (n=41 achieved). Four workshops ran from January-May 2013, each comprising ≈10 mixed staff/SU-EbyE facilitators. Staff training targets were met, but SU-EbyE targets (n=16) were not (achieved: n=12). Four more SU-EbyE were recruited, but did not attend training. Facilitator profession and training attendance are reported in Table 2. Knowledge of ACT, measured by the AKQ, increased significantly (pre-training mean 5.9, SD 3.5; post-training mean 7.4, SD 3.2, t=-3.6, df=31, p=0.003), scores were similar between facilitator groups. All attendees were offered the opportunity to facilitate; 29 did so, all were judged competent to deliver/co-facilitate following training. In-trial and post-trial delivery is shown in Table 2. Eighteen G-ACTp courses (eight service-user, ten caregiver) were delivered over 18 months. Delivery was adherent according to lead therapist observation and rating, and was sufficient to deliver the intended number of groups.

2) Participant recruitment to target (48 service-users; 48 caregivers): partially met

Service-user recruitment reached target (by October 2013); caregiver recruitment required a 6-month extension (to March 2014). Refusals to participate were low (9% of service-users

[10/112]; 5% of caregivers [4/79]), but 13 (4 service-users; 9 caregivers) did not complete baseline having consented.

3) Intervention uptake exceeding current service-based estimates >50%: met

Therapy uptake (attending ≥1 G-ACTp session) for those randomised and offered ACTnow was 84% ([36/43]; 86% of service-users [18/21]; 82% of caregivers [18/22]). Therapy uptake across all trial participants contacted and offered participation was 60% ([74/124]; 64% of service-users [39/61]; 56% of caregivers [35/63]). Attendance ranged from 1-6 sessions for both service-users (Mean=3.9, SD=1.9) and caregivers (Mean=4.4, SD=2.0). Uptake for ACTlater participants post-waitlist was 62% ([21/34]; 70% of service-users [14/20], mean attended=3.85, SD=1.92; 50% of caregivers [7/14], mean attended=4.43, SD=1.74).

4) Retention ≥ 80%: partially met

Follow-up data was available for 78% of those successfully randomised ([66/85]; 82% of service-users [36/44]; 73% of caregivers [30/41]). In practice, one additional ACTlater caregiver was followed up, but assessment data was corrupted, and one ACTnow service-user was excluded, thus 67/84 available participants completed follow-up (80%).

Trial outcomes

1) Adverse events

Adverse events were defined as clinically unexpected deterioration in presentation or harm, identified by participants, treating teams or other informal support, or the research team, that was attributable to study participation. No adverse events were identified during the course of

the study. During five-year follow-up, four participants sadly died, all in the ACTnow group, at 12-, 14-, 29-, and 32-months post-randomisation. The earliest of these post-dated involvement by 6-months, and participation was not implicated in any incident, by any party, including routine internal trust incident investigations.

2) Primary and secondary outcome effects at 4-weeks and 12-weeks

Table 1 shows demographic characteristics by service-user/caregiver status and allocation; summary scores at 0-weeks, 4-weeks and 12-weeks are shown in Tables 3 and 4. Randomly occurring differences between allocation groups were found post-hoc only for PSYRATS delusions and ED attendances, the groups were otherwise comparable, although these analyses were not powered. Table 5 shows estimated treatment effects for the proposed primary outcomes of wellbeing/distress using a linear mixed model (Coefficient=9.6, p=0.07, 95% confidence interval -0.7, 20.0). ESs across outcomes ranged from very small to large, mostly favouring ACTnow, signalling positive effects of intervention. Service users improved on 12 of 13 outcomes measured at 12-weeks, average ES=0.3; and on 11 of 12 outcomes at 4-weeks, average ES=0.4. Caregivers improved on 8 of 9 outcomes measured at 12-weeks, average ES=0.3; and 7 of 9 outcomes at 4-weeks, average ES=0.2.

3) Economic outcomes

Costs were incurred by very few individuals and outcomes were therefore highly variable and should be considered cautiously. Nevertheless, raw costs of emergency/inpatient/crisis service use during the 12-week intervention were £0 for ACTnow (i.e. no emergency/inpatient/crisis use).

Accounting for treatment costs of £590.83/person[2] costs were lower for ACTnow during compared to before treatment, and compared to ACTlater, consistent with potential for cost-effective delivery (Table 4).

4) Acceptability

Satisfaction levels were high; qualitative feedback highlighted positive impact on recovery for service-users and improved resources to manage the caregiving relationship for caregivers (Table 6).

5) Uncontrolled 6-month follow-up

Half of all randomised participants completed uncontrolled 6-month follow-up. Wellbeing and distress outcomes were comparable to post-treatment ACTnow scores, consistent with maintenance of change (wellbeing mean: service-users=45.1 (SD=10.8, n=23), caregivers=50.7 (SD=8.2, n=21); distress mean: service-users=13.0 (SD=7.4, n=23), caregivers=10.0 (SD=6.7, n=21)).

Five-year service use and implementation follow-up

Over five years, uncontrolled costs across participants show small reductions and reduced variability compared to pre-baseline (£743/month, SD=£1930 pre-treatment; £217/person/month SD=£420 post-treatment), suggesting limited, but sustained, savings.

[2] Calculated as: SU-EbyE6 30 hours@£15/hour & frontline mental health staff 30 hours@£52/hour (6 hours training; 6x3 hours delivery + pre/post discussion; 6 hours supervision)=£450 + £1560; lead therapist 24.365 hours @£63/hour (6/7 hours training delivery/18 (groups)*4 (workshops); 6x3 hours delivery + pre/post discussions; 12 hours supervision/12 co-facilitators (6 SU-EbyE; 6 staff); 6 hours peer supervision/2 groups=£1535. Grand total=£3545/group; cost per head assuming 6 participants/group=£590.83.

G-ACTp delivery continued in the host trust across inpatient, community and caregiver support services. Funded dissemination activity included establishing a study resources website (http://actforpsychosis.com), publishing the trial manual (O'Donoghue et al., 2018), a feedback event in Spring 2018, and fulfilling bespoke training requests, leading to additional take-up across London, the UK, and internationally.

Sample size estimation

Pooled variances for wellbeing/distress (98.8 and 58.0 respectively) suggested n=100-300/arm to detect obtained treatment effects with 90% power and α=0.05.

Discussion

We set out to evaluate the feasibility of implementing a model of frontline, recovery-focused training and dissemination of brief ACT groups for psychosis (G-ACTp), and to estimate recruitment and retention rates and variability in outcomes using a pragmatic randomised controlled design in community psychosis services. Feasibility criteria were mostly met for training and delivery, and met for intervention uptake; recruitment and retention criteria were met for service-users but not for caregivers. Indications were of a positive effect of intervention, with high levels of satisfaction and positive feedback, but with relatively small effects on the proposed primary outcomes that suggest sample sizes between n=100-300/arm for a future study. Across outcomes, between-group ESs ranged from very small to large, but average ESs of 0.3-0.4 for service users are commensurate with meta-analyses of longer, individual cognitive behavioural therapies (e.g. NICE, 2014, ES=0.37). Disseminability is supported by sustained delivery, and wider uptake following training. The possibility of successful peer delivery is highlighted and could be further evaluated as the main focus of a

future study. Qualitative feedback from SU-EbyEs was positive and participants highlighted the added value of their lived experience: this will be separately written up. Our findings indicate that SU-EbyE recruitment requires improvement: strategies like presentations to involvement groups may help. Economic outcomes require cautious interpretation, but together with dissemination outcomes, are consistent with potential for cost-effective implementation. However, costs were controlled only during intervention delivery. Uncontrolled follow-up outcomes suggest overall small reductions and reduced variability in longer-term service-use: future research should include a longer controlled evaluation of whether treatment costs are offset by reductions in follow-up service-use.

Effect sizes were slightly larger in service-users compared to caregivers, and either comparable or slightly reduced from 4-weeks to 12-weeks, in line with previous research (Bach et al., 2012), while caregiver outcomes improved from 4-weeks to 12-weeks. The exception to the overall positive trend favouring ACTnow for service-users was PSYRATS delusions; score increases were due to more participants reporting beliefs at follow-up, and allocation groups differed at baseline. While the possibility of the intervention genuinely increasing delusional ideation should not be disregarded, particularly as previous studies suggest outcomes may be less positive for some symptom presentations (e.g. Shawyer et al., 2014), given the context of otherwise positive change, the increase may reflect greater trust in the assessor to share beliefs at follow-up (Bach and Hayes, 2002). For caregivers, the ES for mindfulness was 0 at 4-weeks, and having a full state of health on the EQ-5D appeared to be less likely following intervention, which may have been impacted by the high levels of physical health problems and disability in our caregivers. Findings overall for service-users are consistent with previous randomised evaluations of individual ACT approaches for people with psychosis (e.g. White et al., 2011). Previous findings of improvement from

before to after group ACT intervention are extended by demonstrating similar treatment effects in comparison to a control condition and employing a randomised design (Johns et al., 2015). The emerging evidence base for caregivers of people with a range of long-term conditions (e.g. Losada et al., 2015) is similarly extended by the current findings, indicating that group ACT approaches have potential to improve wellbeing for caregivers of people with psychosis, and therefore comprise an intervention that could be delivered in routine services to support caregivers, in line with UK NICE recommendations. However, recruitment and retention of caregivers was problematic, primarily because of engagement difficulties, caregiving responsibilities, and other commitments, and our findings suggest that more time should be allowed for recruitment, and greater attrition expected, in caregiver compared to service-user participants. The suggestion of slightly different trajectories for service-users and caregivers could be explicitly tested in a future study, but the overall similarity in outcomes is consistent with the orientation of the ACT model towards common human processes, rather than those characterising psychopathology. Change in process measures was consistent with outcome change, and feedback highlights the accessibility of ACT constructs, as in previous qualitative studies (Bacon, Farhall, Fossey, 2014). Because of the wide applicability of ACT approaches, training has greater potential to result in wider-scale implementation compared to condition-specific interventions with different competences according to presenting problems.

Limitations

An important methodological limitation of the study was that assessments were not blind, either at follow-up or at baseline, as participants were randomised at the point of consent, although only informed of their allocation after completion of the baseline assessment. This

was because the in-service setting for the trial made blind assessment logistically difficult. Nevertheless, the assessor was independent of therapy delivery, and the primary outcomes were self-reported, rather than rated by the assessor. We have found in subsequent studies that blind assessment can be achieved by an additional assessor working alongside the study research worker but solely on follow-up assessments (i.e. without any other liaison with participants, and wholly separate from the clinical team and research therapists).

External adherence ratings were not obtained, as audiorecording for this purpose required consent from every group member, which was not given in this study (and, in our experience, is a common difficulty). Lead therapists were, however, expert in the intervention, trained to competence in previous trials (Johns et al., 2015) and followed a strict protocol, overseeing the work of their co-facilitators, and attending peer supervision sessions. We were, therefore, confident that the intervention was delivered as intended, but recognise the need for formal and objective evaluations of adherence in future research, for example, through a priori arrangements for live independent observation. This will be particularly important for studies of the effectiveness of dissemination beyond services with specific ACT expertise.

We did not examine effects of medication status and did not record changes, or receipt of other interventions, and relied, without post hoc testing, upon randomisation to adequately control for any unintended differences between groups in these variables. Only two randomly occurring baseline differences between allocation groups reached significance, but the study was not powered to test baseline differences, which may therefore have gone undetected. The loss of participants, through non-adherence to allocation and loss to follow-up elevates the risk of bias in the study, and, while predictors of missing data were controlled in the analyses, data were not missing at random: replication will be required. The study was

small, with multiple outcomes, and not designed to test efficacy. Economic outcomes reflected service use by a small number of individuals, and were highly variable, requiring cautious interpretation. Recruitment took place in a single service, using service parameters for inclusion, and applicability in other contexts has not been tested. We also did not compare the intervention to an active control condition, and therefore cannot, on the basis of current findings, attribute change to specific ACT processes, rather than generic components of the intervention. Subsequent analyses of mechanisms of change will partially address this issue, but future research should employ a larger sample, recruited across multiple sites, powered for subgroup analyses, and include comparison to a routinely available control intervention. Cluster randomisation and sessional outcome completion may reduce the risk of bias through difficulty adhering to allocation and loss to follow-up: the high risk of bias in the current study limits interpretation of the size of effects, which should in any case be treated cautiously in a pilot, but should not impact variability of outcomes or other feasibility estimations. Our dissemination evaluation, beyond initial staff and SU-EbyE training, was observational, and participation voluntary, without selection criteria. While sustained delivery in the host service and wider uptake are positive indications, formal evaluation of implementation, including uptake, competence and effectiveness of delivery, will be required, and selection criteria (e.g. permanent staff) should be applied. Controlled economic outcomes were collected over a very short time frame (3-months), and future research should extend this.

Conclusions

Implementation of our new group ACT intervention was feasible, with adjustment to allow for slower recruitment and poorer follow-up for caregivers. Satisfaction and feedback were

good and preliminary treatment effects were consistent with positive impact of intervention. The study had some methodological limitations, notably loss to follow-up introducing risk of bias, unblinded assessments, and a lack of formal assessments of adherence. Future research should address these, incorporating an active control, longer controlled economic follow-up, and a planned investigation of potential differences in treatment response trajectories between service-users and caregivers. However, considering the brief format of the group, and ease of frontline delivery, early indications from this preliminary study suggest potential for wider, cost-effective implementation.

Figure 1: Consort diagram showing the flow of recruitment and retention in the study

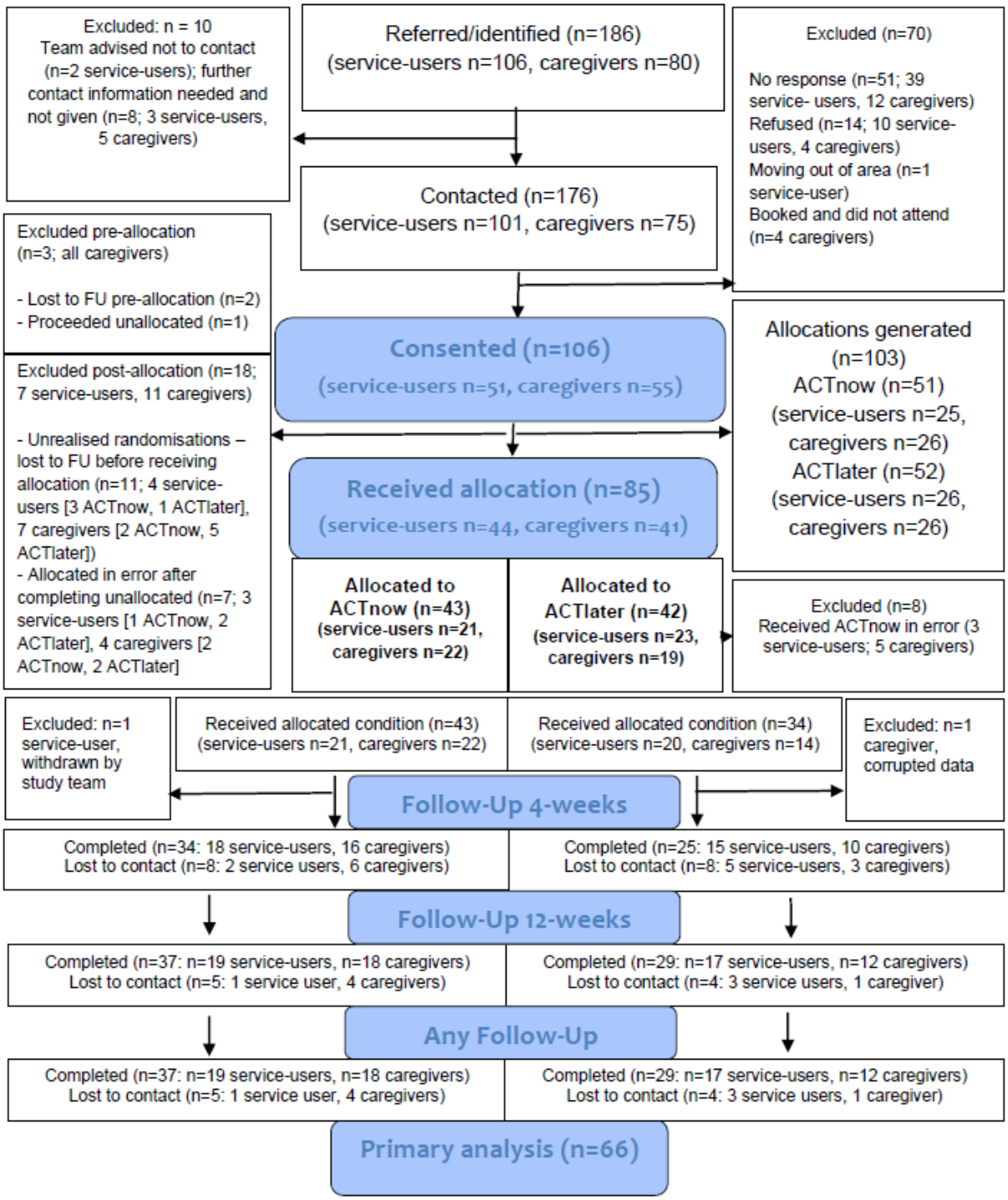

Table 1. Demographic and clinical characteristics by intervention group and service-user/caregiver status.

Demographic/clinical characteristic	**Intervention group/status**			
	ACT now *(n=43)*		**ACT later** *(n=42)*	
	Service-user *(n=21)*	**Caregiver** *(n=22)*	**Service-user** *(n=23)*	**Caregiver** *(n=19)*
Age (years) Mean (SD)	43.3 (9.8)	52.7 (9.1)	43.1 (12.1)	50.5 (14.4)
Gender, n (%) Male:Female	9:12 (43:57)	1:21 (5:95)	11:12 (48:52)	3:16 (16:84)
Ethnicity, n (%) BME:Non-BME	11:10 (52:48)	10:11[1] (52:48)	16:7 (70:30)	10:9 (53:47)
Ever married, Yes:No, n (%)	11:9 (55:45)	-	19:3 (86:14)	-
Living alone, Yes:No, n (%)	14:4 (78:22)	-	12:9 (57:43)	-
Further education, Yes:No, n (%)	10:10 (50:50)	-	10:13 (44:56)	-
Medication, n (%)[2]				
- Antipsychotic	11 (76)		10 (76)	
- and antidepressant	4 (24)		4 (24)	
- and mood stabiliser	2 (12)		3 (18)	
Caregiving Relationship, n (%) [caregiver is a(n)…]				
- Parent		11 (50)		8 (42)
- Sibling		2 (9)		1 (5)
- Adult child		1 (4)		3 (16)
- Spouse/partner		2 (9)		2 (11)
- Other family member		4 (18)		1 (5)
- Friend		1 (4)		3 (16)
- Not stated		1 (4)		1 (5)
Diagnosis, n (%)				
- Schizophrenia spectrum	14 (67)		9 (40)	
- Bipolar/mania	1 (4)		7 (30)	
- Other[3]	6 (29)		7 (30)	

Key: SD: Standard deviation; BME: Black and minority ethnic; [1]one caregiver preferred not to state their ethnicity; [2]medication data collected for n=17 ACTnow, n=17ACTlater; [3]'Other' other affective or behavioural presentation, diagnoses included psychotic symptoms in the context of severe depression (n=8); severe anxiety disorder (n=2); personality disorder (n=1); eating disorder (n=2); no diagnosis specified (n=3).

Table 2. Training participants and delivery.

	SU-EbyE	Permanent Staff	Temporary staff/trainees	Total
Recruited	16	21	8	45
Attended workshop	12	21	8	41
Role -Nurse -Social worker -Occupational therapist -Carer support worker -Psychologist -Assistant psychologist		 2 1 5 1 11 1	 1 7	
Completed any AKQ	11	19	7	37
In-trial delivery (≥1 group) -No groups -One group -Two groups -Three groups -Four groups	12 0 8 3 0 1	14 5 13 1 0 0	3 5 3 0 0 0	29
Total groups delivered	18	15	3	18
Discontinued training	0	0	0	0
Judged competent post-training	12	14	3	29
Post-trial delivery at 20-weeks -None -To protocol -Adapted	2 10 2 0	11 3 7 4	2 1 2 0	14[1]

Key: SU-EbyE: Service user expert by experience; AKQ: Acceptance and Commitment Therapy Knowledge Questionnaire; [1]One SU-EbyE ran a group with a permanent staff member

Table 3. Common measures at 0, 4 and 12 week assessments for service-users and caregivers by intervention group.

Measure/status/ Group		**Mean wellbeing/functioning score by assessment (SD)**						**Between group ES**	**Between group ES**
WEMWBS		*N*	**Week-0**	*n*	**Week-4**	*n*	**Week-12**	**0-4 week [95%CI]**	**0-12 week [95%CI]**
SU	**ACTnow**	*19*	44.3 (13.1)	*17*	46.6 (11.5)	*18*	45.7 (10.4)	0.4 [-0.4, 1.2]	0.1 [-0.6, 0.8]
	ACTlater	*23*	41.1 (10.0)	*14*	39.4 (10.1)	*17*	41.1 (12.1)		
CG	**ACTnow**	*22*	47.3 (8.8)	*16*	47.4 (9.8)	*17*	48.4 (7.8)	0.3 [-0.6, 1.2]	0.3 [-0.5, 1.1]
	ACTlater	*18*	46.9 (9.7)	*9*	44.6 (10.2)	*10*	45.5 (8.0)		
CORE-10									
SU	**ACTnow**	*20*	16.7 (9.3)	*18*	12.6 (6.4)	*18*	14.6 (8.3)	-0.5 [-1.2, 0.2]	-0.4 [-1.1, 0.3]
	ACTlater	*23*	14.9 (7.2)	*15*	14.9 (7.0)	*17*	16.3 (8.4)		
CG	**ACTnow**	*22*	12.4 (6.5)	*16*	10.6 (7.1)	*17*	9.0 (5.5)	-0.1 [-0.9, 0.7]	-0.4 [-1.2, 0.4]
	ACTlater	*17*	13.5 (6.8)	*10*	12.1 (8.8)	*12*	12.8 (8.0)		
Interference									
SU	**ACTnow**	*20*	17.7 (6.6)	*18*	14.3 (6.4)	*19*	15.6 (7.8)	-0.7 [-1.5, 0.1]	-0.6 [-1.3, 0.1
	ACTlater	*23*	18.1 (7.8)	*14*	19.5 (7.1)	*16*	20.4 (6.7)		
CG	**ACTnow**	*21*	12.4 (7.8)	*16*	9.2 (7.3)	*17*	9.0 (7.4)	-0.4 [-1.2, 0.4]	-0.5 [-1.3, 0.3]
	ACTlater	*18*	12.7 (7.3)	*10*	12.8 (9.4)	*12*	13.3 (7.3)		
Time Budget Measure									
SU	**ACTnow**	*17*	60.3 (12.7)	*17*	67.8 (13.0)	*18*	65.1 (15.8)	1.0 [0.2, 1.8]	0.3 [-0.4, 1.02]
	ACTlater	*21*	59.5 (13.2)	*15*	53.4 (13.5)	*15*	59.7 (18.1)		
CG	**ACTnow**	*17*	74.8 (18.3)	*15*	75.5 (16.1)	*17*	84.6 (13.6)	-0.3 [-1.2, 0.6]	0.5 [-0.3, 1.3]
	ACTlater	*16*	74.4 (18.0)	*10*	79.4 (17.4)	*12*	76.5 (15.7)		
EQ-5D health thermometer									
SU	**ACTnow**	*20*	61.1 (17.6)	*18*	63.2 (22.9)	*19*	66.6 (20.8)	0.2 [-0.5, 0.9]	0.2 [-0.5, 0.9]
	ACTlater	*21*	57.6 (19.4)	*15*	55.7 (18.9)	*17*	59.2 (19.5)		
CG	**ACTnow**	*21*	70.3 (20.3)	*14*	72.1 (16.8)	*16*	75.5 (18.3)	0.4 [-0.5, 1.3]	0.4 [-0.4, 1.2]
	ACTlater	*18*	73.1 (21.8)	*9*	67.2 (20.8)	*12*	69.6 (22.4)		
EQ-5D proportion with a full state of health[1]									
SU	**ACTnow**	*20*	20%	*18*	17%	*19*	16%	0.2 [-0.5, 0.9]	0.6 [-0.1, 1.3]
	ACTlater	*22*	9%	*15*	13%	*17*	6%		
CG	**ACTnow**	*21*	14%	*16*	6%	*17*	18%	-1.0 [-1.9, -0.1]	-0.2 [-1.0, 0.6]
	ACTlater	*18*	11%	*10*	30%	*12*	25%		
Acceptance									
SU	**ACTnow**	*18*	31.5 (11.7)	*18*	28.3 (11.0)	*19*	28.8 (10.8)	-0.6 [-1.3, 0.1]	-0.4 [-1.1, 0.3]
	ACTlater	*23*	29.3 (8.1)	*15*	31.7 (9.3)	*17*	30.4 (10.0)		
CG	**ACTnow**	*21*	22.3 (9.7)	*14*	19.8 (5.3)	*16*	18.7 (6.0)	-0.5 [-1.4, 0.4]	-0.6 [-1.4, 0.2]
	ACTlater	*18*	21.4 (8.8)	*10*	23.4 (9.8)	*12*	23.3 (10.3)		
Valuing									
SU	**ACTnow**	*17*	24.7 (11.4)	*18*	26.9 (10.2)	*19*	24.6 (11.6)	0.3 [-0.4, 1.0]	0.1 [-0.6, 0.8]
	ACTlater	*22*	22.5 (9.0)	*14*	21.4 (8.5)	*17*	21.6 (11.8)		
CG	**ACTnow**	*20*	27.7 (8.2)	*15*	30.9 (6.8)	*17*	31.3 (7.4)	0.6 [-0.3, 1.5]	0.4 [-0.4, 1.2]
	ACTlater	*17*	28.8 (8.5)	*10*	26.8 (9.9)	*12*	28.7 (10.1)		
Mindfulness									
SU	**ACTnow**	*18*	39.5 (20.1)	*17*	46.2 (21.2)	*19*	45.2 (21.0)	0.6 [-0.1, 1.3]	0.6 [-0.1, 1.3]
	ACTlater	*23*	44.4 (17.0)	*15*	39.2 (16.9)	*17*	38.8 (18.3)		
CG	**ACTnow**	*21*	56.4 (16.4)	*15*	60.2 (13.4)	*16*	64.4 (14.0)	0 [-0.8, 0.8]	0.2 [-0.6, 1.0]
	ACTlater	*18*	54.1 (12.6)	*10*	58.1 (13.9)	*11*	59.9 (12.0)		

Key: SU: Service-user; CG: Caregiver; SD: Standard deviation; ES: Effect size. [1]ES calculated as difference in proportions at each time point, not change over time.

Table 4. Service-user only measures at 0, 4 and 12 week assessments by intervention group.

Measure/ group	Mean wellbeing/functioning score by assessment (SD)						Between group ES	Between group ES
	n	Week-0	*n*	Week-4	*n*	Week-12	0-4 week [95%CI]	0-12 week [95%CI]
Recovery								
ACTnow	*18*	56.3 (16.6)	*18*	58.3 (17.0)	*18*	59.3 (14.1)	0.3 [-0.4, 1.0]	0.3 [-0.4, 1.0]
ACTlater	*21*	52.4 (14.6)	*14*	50.1 (12.7)	*17*	50.6 (16.7)		
Voices								
ACTnow	*19*	9.7 (13.4)	*18*	5.9 (11.3)	*18*	5.5 (11.3)	-0.8 [-1.5, -0.1]	-0.4 [-1.1, 0.3]
ACTlater	*23*	7.0 (12.5)	*15*	14.3 (16.1)	*15*	7.6 (13.1)		
Delusions								
ACTnow	*19*	0[4]	*18*	2.8 (5.6)	*18*	2.4 (5.8)	0.4 [-0.3, 1.1]	0.2 [-0.5, 0.9]
ACTlater	*23*	2.2 (6.0)[4]	*15*	2.4 (6.3)	*15*	3.5 (7.3)		
Use/cost/ Group	**Economic outcomes (raw totals for those with service use only)**							
	n	**E1: -12 to 0 months**	*n*	**E2: -12 to 0 weeks**	*n*	**E3: 0 to 12 weeks**	**60 months**	**Raw change E1-E3, E2-E3**
Emergency Department Attendances (number)								
ACTnow	*4*	5[4]	*0*	0	*0*	0	36	-5, 0
ACTlater	*0*	0[4]	*0*	0	*1*	1		0, 1
Psychiatric inpatient admissions (number)								
ACTnow	*6*	7	*2*	2	*0*	0	30	-7, -2
ACTlater	*3*	7	*2*	2	*1*	1		-6, -1
Occupied bed days (number)								
ACTnow	*6*	477	*2*	41	*0*	0	896	-477, -41
ACTlater	*3*	125	*2*	40	*1*	16		-109, -24
Days under the crisis team (total)								
ACTnow	*5*	108	*0*	0	*0*	0	549	-108, 0
ACTlater	*4*	98	*0*	0	*3*	63		-35, 63
Total costs of care[1] (£)								
ACTnow	*7*	294365	*2*	17137	*0*	0	573425	-294365, -17137
ACTlater	*5*	89044	*2*	16640	*3*	30668		-58376, 14028
With total intervention cost (£591/person)[3]								
ACTnow					*21*	12411		-281954, -4726
	Economic costs (mean £/person/month[2], with intervention cost £591/3)[3]							**Mean change E1-E3, E2-E3 [95% CIs]**
ACTnow	*21*	1168 (2556)	*21*	272 (938)	*21*	197 (0)	217 (420)	-971, -75 [-2064, 122] [-476, 326]
ACTlater	*23*	323 (917)	*23*	241 (803)	*20*	511 (1282)		189, 270 [-459, 837] [-417, 957]
Between group ES (d) [95% CI]		0.4 [-0.2, 1.2]		0.04 [-0.6, 0.7]		-0.4 [-1.0, 0.2]	-	-0.6, -0.3 [-1.35, 0.05] [-0.9, 0.3]

Key: SD: Standard deviation; ES: Effect size. [1]Costs are the total emergency/inpatient/crisis service usage, costed according to the Personal Social Services Research Unit costs of health and social care (PSSRU, Curtis & Burns, 2016; 2018) and NHS reference costs (Department of Health, 2011; 2016). [2]Costs/person/month (i.e. /12 at -12 months-0-weeks; /3 at -12 weeks-0 weeks and 0-12 weeks; /60 at 60_months; 0' costs represent no emergency/inpatient/crisis use; [3]Intervention cost based on 6 individuals/group. [4]Baseline scores differ by chance by a significantly large amount, p<0.05.

Table 5: *Mixed linear model estimating average treatment effects on overall wellbeing outcomes (n=66).*

Predictor	Coefficient	SE	z score	p	95% CI
Allocation (ACTnow/later)	9.6	5.3	1.8	0.07	-0.7, 20.0
Status (Service-user/Caregiver)	-4.8	4.4	-1.1	0.3	-13.4, 3.8
Baseline wellbeing	0.03	0.2	0.15	0.9	-0.3, 0.4
Baseline distress	0.4	0.4	1.0	0.3	-0.4, 1.1
Measure (wellbeing/distress)	-25.8	3.1	-8.5	<0.001	-31.8, -19.9
Time (4/12 weeks)	14.1	4.6	3.1	0.002	5.1, 23.1
Allocation x Time interaction term[1]	-7.2	6.2	-1.2	0.2	-19.3, 4.8

Key: SE: standard error; CI: confidence interval; ACT: Acceptance and Commitment Therapy. [1]Removing the interaction term, the overall effect of Allocation across the two time points (4 and 12 weeks) was found to be: Coefficient=6.1; SE=4.3; z score=1.4; p=0.2; 95%CI=-2.3, 14.5

Table 6: ACT for Recovery treatment group self-rated satisfaction and feedback.

Satisfaction item	**Mean (Standard Deviation)**		
(Range 1 [poor] to 4 [excellent])	Service-User (n=15)	Caregiver (n=15)	Total (n=30)
How would you rate the quality of the workshops you have attended?	3.8 (0.4)	3.8 (0.4)	3.8 (0.4)
Have you been able to take something from the workshops and use it in your life?	3.9 (0.3)	3.9 (0.3)	3.9 (0.3)
Have the workshops helped you deal more effectively with your problems?	3.3 (0.6)	3.5 (0.5)	3.4 (0.6)
In an overall, general sense, how satisfied are you with the workshops?	3.6 (0.5)	3.5 (0.5)	3.5 (0.5)
How satisfied are you about the therapists running the workshops?	3.3 (1.0)	3.9 (0.4)	3.6 (0.8)
Would you come back to a workshop like this again?	3.5 (0.6)	3.8 (0.4)	3.7 (0.5)
Did the workshops help you find out what is important to you?	3.6 (0.6)	3.7 (0.6)	3.6 (0.6)
If a friend or someone you knew were in need of similar help, would you recommend the workshops to him/her?	3.7 (0.6)	3.8 (0.4)	3.7 (0.5)
Qualitative feedback			
Service-user feedback: Impact on recovery	Sharing experiences with others; good outlook on how to deal with problems; working towards what's important; identifying what's important; taking things in small steps; more aware of passengers/moods/thoughts; better coping; changed outlook; new way to face situations; more motivated; more assertive; moving forward; doing more		
Caregiver feedback: Impact on caregiving relationship	Sharing experiences with others; relaxing; facing and dealing with problems; how to react and look at things; don't need to feel guilty; different way of responding; give more space; taking care of self to care better; taking time for self; less worried and anxious; realise others can help		

References

A-Tjak, J.G.L., Davis, M. L., Morina, N., Powers, M. B., Smits, J. A. J., & Emmelkamp, P. M. G. (2014). A meta-analysis of the efficacy of acceptance and commitment therapy for clinically relevant mental and physical health problems. *Psychotherapy and Psychosomatics, 84*, 30-36.

Bach, P., Hayes, S.C. (2002). The use of acceptance and commitment therapy to prevent the rehospitalization of psychotic patients: a randomized controlled trial. *Journal of Consulting and Clinical Psychology*, 70, 1129-39.

Bach, P., Hayes, S.C., & Gallop, R. (2012). Long term effects of brief Acceptance and Commitment Therapy for psychosis. *Behavior Modification, 36*, 167–183.

Bacon, T., Farhall, J., & Fossey, E. (2014). The active therapeutic processes of acceptance and commitment therapy for persistent symptoms of psychosis: clients' perspectives. Behavioural and cognitive psychotherapy, 42(4), 402–420. https://doi.org/10.1017/S1352465813000209

Barkham, M., Bewick, B., Mullin, T., et al. (2013). The CORE-10: A short measure of psychological distress for routine use in the psychological therapies. *Counselling & Psychotherapy Research, 13*, 3-13.

Barton, G.R., Hodgekins, J., Mugford, M., Jones, P.B., Croudace, T., Fowler, D. (2009). Measuring the benefits of treatment for psychosis: validity and responsiveness of the EQ-5D. British Journal of Psychiatry, 195,170-177. doi:10.1192/bjp.bp.108.057380

Broyd, A., Jolley, S., Johns, L. (2016). Determinants of subjective wellbeing in people with psychosis referred for psychological therapy in South London. *British Journal of Clinical Psychology, 55,* 429-40.

Butler, L., Johns, L.C., Byrne, M., Joseph C., O'Donoghue, E., Jolley, S., Morris, E., Oliver. J. (2016). Running acceptance and commitment therapy groups for psychosis in community settings. *Journal of Contextual & Behavioural Science, 5,* 33-8.

Carr, S. (2016). Position Paper: Are mainstream mental health services ready to progress transformative co-production? The National Development Team For Inclusion. https://www.ndti.org.uk/uploads/files/MH_Coproduction_position_paper.pdf . Last accessed 23rd May, 2020.

Castilho, P., Martins, M. J., Pinto, A. M., Viegas, R., Carvalho, S., & Madeira, N. (2017). Understanding the effect of attachment styles in paranoid ideation: The mediator role of experiential avoidance. Journal of Contextual Behavioral Science, 6(1), 42-46.

Chong, H. Y., Teoh, S. L., Wu, D. B., Kotirum, S., Chiou, C. F., & Chaiyakunapruk, N. (2016). Global economic burden of schizophrenia: a systematic review. Neuropsychiatric disease and treatment, 12, 357–373. doi:10.2147/NDT.S96649

Connell, J. & Barkham, M. (2007). CORE-10 User Manual, Version 1.1. CORE System Trust & CORE Information Management Systems Ltd.

Cramer, H., Lauche, R., Haller, H., Langhorst, J., & Dobos, G. (2016). Mindfulness-and Acceptance-based Interventions for Psychosis: A Systematic Review and Meta-analysis. *Global Advances in Health and Medicine, 5,* 30-43.

Curtis, L. & Burns, A. (2018) Unit Costs of Health and Social Care 2018, Personal Social Services Research Unit, University of Kent, Canterbury. https://doi.org/10.22024/UniKent/01.02.70995

Curtis, L. & Burns, A. (2016) Unit Costs of Health and Social Care 2016, Personal Social Services Research Unit, University of Kent, Canterbury.

Department of Health. (2018) NHS reference costs 2015 to 2016: National schedule of reference costs: the main schedule. Available at: https://www.gov.uk/government/ publications/nhs-reference- costs-2015- to-2016.

Department of Health (2011). National Survey of Investment in Adult Mental Health Services. Available at: https://assets.publishing.service.gov.uk/government/ uploads/system/uploads/attachment_data/file/216591/dh_130861.pdf

Davis, E.L., Deane, F.P., Lyons, G.C. (2015). Acceptance and valued living as critical appraisal and coping strengths for caregivers dealing with terminal illness and bereavement.

Palliative and Supportive Care, 13, 359-68.

Dixon, L.B., Dickerson, F., Bellack, A.S., et al., (2010). Schizophrenia Patient Outcomes Research Team (PORT). The 2009 schizophrenia PORT psychosocial treatment recommendations and summary statements. *Schizophrenia Bulletin, 36,* 48-70.3

Shawyer, F., Farhall, J., Mackinnon, A., Trauer, T., Sims, E., Ratcliff, K., Larner, C., Thomas, N., Castle, D., Mullen, P., & Copolov, D. (2012). A randomised controlled trial of acceptance-based cognitive behavioural therapy for command hallucinations in psychotic disorders. Behaviour research and therapy, 50(2), 110–121. https://doi.org/10.1016/j.brat.2011.11.007

Garety, P.A., Fowler, D.G., Freeman, D., Bebbington, P.E., Dunn, G., & Kuipers, E. (2008). Cognitive-behavioural therapy and family intervention for relapse prevention and symptom reduction in psychosis: A randomised controlled trial. *British Journal of Psychiatry, 192,* 412-423.

Gloster, A. T., Meyer, A. H., & Lieb, R. (2017). Psychological flexibility as a malleable public health target: Evidence from a representative sample. Journal of Contextual Behavioral Science, 6(2), 166-171.

Gühne U, Weinmann S, Riedel-Heller SG, Becker T. (2020). Psychosocial therapies in severe mental illness: update on evidence and recommendations. [published online ahead of print, 2020 May 13]. Curr Opin Psychiatry. doi:10.1097/YCO.0000000000000618

Hayes, S. C., Luoma, J. B., Bond, F. W., Masuda, A., & Lillis, J. (2006). Acceptance and commitment therapy: Model, processes and outcomes. *Behaviour Research and Therapy, 44,* 1-25.

Hayes, S. C., Strosahl, K. D., & Wilson, K. G. (2012). Acceptance and Commitment Therapy: The Process and Practice of Mindful Change. New York: Guilford Press.

Ince P, Haddock G, Tai S. (2015). A systematic review of the implementation of recommended psychological interventions for schizophrenia: Rates, barriers, and improvement strategies. Psychology & Psychotherapy, 89, 324-50. doi: 10.1111/papt.12084.

Jansen, J. E., Haahr, U. H., Lyse, H. G., Pedersen, M. B., Trauelsen, A. M., & Simonsen, E. (2017). Psychological flexibility as a buffer against caregiver distress in families with psychosis. Frontiers in psychology, 8, 1625.

Jansen, E.J., Gleeson, J., Bendall, S., Rice, S., & Alvarez-Jimenez, M. (2019). Acceptance- and mindfulness-based interventions for persons with psychosis : A systematic review and meta-analysis. Schizophrenia Research, (xxxx). https://doi.org/10.1016/j.schres.2019.11.016

Jauhar, S., Mckenna, P.J., Radua, J., et al. (2014). Cognitive-behavioural therapy for the symptoms of schizophrenia: systematic review and meta-analysis with examination of potential bias. *British Journal of Psychiatry, 204,* 20-29.

Johns, L.C., Oliver, J.E., Khondoker, M., et al. (2015). The feasibility and acceptability of a brief Acceptance and Commitment Therapy (ACT) group intervention for people with psychosis: the 'ACT for Life' study. *Journal of Behavior Therapy and Experimental Psychiatry, 50,* 257-263.

Jolley, S., Garety, P., Peters, E., Fornells-Ambrojo, M., Onwumere, J., Harris, V., Brabban, A. & Johns, L. (2015). Opportunities and challenges in Improving Access to Psychological Therapies for people with Severe Mental Illness (IAPT-SMI): Evaluating the first operational year of the South London and Maudsley (SLaM) demonstration site for psychosis. *Behaviour Research and Therapy, 64,* 24-30.

Kashdan, T. B., & Rottenberg, J. (2010). Psychological flexibility as a fundamental aspect of health. *Clinical Psychology Review, 30,* 865-878

Khoury, B., Lecomte, T., Gaudiano, B. A., & Paquin, K. (2013). Mindfulness interventions for psychosis: a meta-analysis. *Schizophrenia Research, 150,* 176-184.

Kishita, N., Hammond, L., Dietrich, C. M., & Mioshi, E. (2018). Which interventions work for dementia family carers?: an updated systematic review of randomized controlled trials of carer interventions. International psychogeriatrics, 30(11), 1679-1696.

Kuipers, E., Onwumere, J., and Bebbington, P. (2010). Cognitive model of caregiving in psychosis. *British Journal of Psychiatry, 196,* 259-65.

Losada, A., Márquez-González, M., Romero-Moreno, R., Mausbach, B.T., López, J., Fernández-Fernández, V. & Nogales-González, C. (2015). Cognitive-behavioral therapy (CBT) versus acceptance and commitment therapy (ACT) for dementia family caregivers with significant depressive symptoms: Results of a randomized clinical trial. *Journal of Consulting and Clinical Psychology*, *83*, 760-72.

Louise, S., Fitzpatrick, M., Strauss, C., Rossell, S. L., & Thomas, N. (2018). Mindfulness-and acceptance-based interventions for psychosis: our current understanding and a meta-analysis. Schizophrenia Research, 192, 57-63.

Luoma, J.B., Vilardaga, J.P. (2013). Improving therapist psychological flexibility while training acceptance and commitment therapy: a pilot study. Cognitive Behaviour Therapy, 42:1, 1-8, DOI: 10.1080/16506073.2012.701662

Morris, E. (2013). Psychological flexibility and auditory hallucinations. Unpublished doctoral thesis, King's College London, UK.

Morris., E.M.J., Johns, L.C., Oliver, J.E. (2013). Acceptance and Commitment Therapy and Mindfulness for Psychosis. Wiley Blackwell, London.

National Institute for Health & Care Excellence. (2014). Psychosis and Schizophrenia in adults. National Collaborating Centre for Mental Health, London.

O'Donoghue, E. K., Morris, E. M., Oliver, J., & Johns, L. C. (2018). ACT for psychosis recovery: A practical manual for group-based interventions using acceptance and commitment therapy. New Harbinger Publications.

Ost, L.G. (2014). The efficacy of Acceptance and Commitment Therapy: An updated systematic review and meta-analysis. *Behavior Research & Therapy, 61*, 105-121.

Richards, R., Oliver, J. E., Morris, E., Aherne, K., Iervolino, A. C., & Wingrove, J. (2011). Acceptance and Commitment Therapy training for clinicians: an evaluation. The Cognitive Behaviour Therapist, 4, 114–121. https://doi.org/10.1017/S1754470X11000043

StataCorp (2011). Stata Statistical Software: Release 12. College Station, TX: StataCorp LP.

Stewart-Brown, S., & Janmohamed, K. (2008). Warwick-Edinburgh Mental Well-being Scale: User Guide. Version 1. *From http://www.healthscotland.com/documents/2702.aspx*

Tennant, T., Hiller, L., Fishwick, R., et al. (2007). The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): Development and UK validation. *Health & Quality of Life Outcomes*, 5, 63

The Schizophrenia Commission. (2012). The abandoned illness: a report from the Schizophrenia Commission. London: Rethink Mental Illness.

Thomas, N. (2015). What's really wrong with cognitive behavioral therapy for psychosis? Frontiers in Psychology, 6, 323.doi: 10.3389/fpsyg.2015.00323

Toussaint, L., Barry, M., Bornfriend, L., & Markman, M. (2014). Restore: the journey toward self-forgiveness: a randomized trial of patient education on self-forgiveness in cancer patients and caregivers. *Journal of Health Care and Chaplaincy, 20*, 54-74.

Udachina, A., Varese, F., Myin-Germeys, I., & Bentall, R. P. (2014). The role of experiential avoidance in paranoid delusions: an experience sampling study. British Journal of Clinical Psychology, 53(4), 422-432.

Valiente, C., Provencio, M., Espinosa, R., Duque, A., & Everts, F. (2015). Insight in paranoia: The role of experiential avoidance and internalized stigma. Schizophrenia research, 164(1-3), 214-220.

Varese, F., Morrison, A. P., Beck, R., Heffernan, S., Law, H., & Bentall, R. P. (2016). Experiential avoidance and appraisals of voices as predictors of voice-related distress. British Journal of Clinical Psychology, 55(3), 320-331.

Wallace, D. P., Woodford, B., & Connelly, M. (2016). Promoting psychological flexibility in parents of adolescents with chronic pain: Pilot study of an 8-week group intervention. Clinical practice in pediatric psychology, 4(4), 405.

White, I.R., Horton, N.J., Carpenter, J., Pocock, S. (2011). Strategy for intention to treat analysis in randomised trials with missing outcome data. *British Medical Journal, 342,* 910-912.

White R, Gumley A, McTaggart J, Rattrie L, McConville D, Cleare S, Mitchell G. (2011). A feasibility study of Acceptance and Commitment Therapy for emotional dysfunction following psychosis. *Behaviour Research & Therapy, 49,* 901-7.

Appendix I. ACT for Recovery: Assessments and completion protocol

Staff and SU-EbyE co-facilitator measures	**Completed at:**
Knowledge of ACT (Luoma, see Richards et al., 2011)	1,2,3
ACT adherence scale (Morris, 2013)[a]	2,3[a]
Delivery post-training[b]	4[b]
Service-user & caregiver measures	**Completed at:**
Proposed primary outcomes	
Positive wellbeing: Warwick-Edinburgh Wellbeing Scale (WEMWBS, Tennant et al., 2007; Stewart-Brown & Janmohamed, 2008)[c]	1,2,3[c]
Distress: Clinical outcomes in Routine Evaluation (CORE-10, Barkham et al., 2008; Connell and Barkham, 2007)[c]	1,2,3[c]
Functioning outcomes	
Interference measure (adapted from Sheehan, 1983)	1,2,3
Time Budget Activity (Jolley et al., 2005; 2006)	1,2,3
Health-related Quality of Life: EQ5D (EuroQol Group, 1990)	1,2,3
Process measures	
Valuing Questionnaire (VQ-8, Smout et al., 2014)	1,2,3
Acceptance and Action Questionnaire-II (AAQ, Bond et al., 2011)	1,2,3
Southampton Mindfulness Questionnaire (SMQ, Chadwick et al., 2008)	1,2,3
Satisfaction & qualitative outcomes	
Satisfaction Questionnaire (adapted from Attkisson & Zwick,1982)[d]	2[d]
Subjective impact on service-user recovery & caregiving relationship	3
Service-user only measures[e]	**Completed at:**
Questionnaire about the Process of Recovery (QPR, Neil et al., 2009)	1,2,3
Psychotic Symptom Rating Scale (Voices and Beliefs; PSYRATS, Haddock et al., 1999)	1,2,3
Researcher-rated measures[f]	
Client service receipt inventory (Beecham & Knapp, 1992)[g]	1,3[g]
Service use in preceding 3-months[g]	1,3[g]

Timepoints: 1= Baseline; 2=4-weeks; 3=12-weeks; 4=20-weeks

Key: SU-EbyE: Service user expert by experience; [a]adherence was measured sessionally; [b]delivery post-training was also assessed at 5-year-FU; [c]proposed primary outcomes repeated uncontrolled 6-months post-treatment; [c]satisfaction ratings were only collected at 4-weeks and not at 12-weeks; [e]visual analogue ratings of the possibility of being mistaken and the power of the voices were listed in the protocol but in practice omitted from measures packs; [f]the Health of the Nation Outcome Scale (Wing et al., 1996) was intended to be collected from the medical record by the researcher, but was not reliably completed by services and therefore was not collected; [g]service receipt data was in practice restricted to that which could be verified from the medical record, and was also calculated for 12-months pre-baseline, and (uncontrolled) 5-year-FU.

Appendix II: CONSORT checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	5
	2b	Specific objectives or research questions for pilot trial	6
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	10
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	11
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6,7
	4c	How participants were identified and consented	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	12,18
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-12, 24
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	24
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	10/11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	11
	11b	If relevant, description of the similarity of interventions	12
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	8-12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	14,15
	13b	For each group, losses and exclusions after randomisation, together with reasons	13,23
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7,14
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	25
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	16,23
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	26,27
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	19
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	17-20
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	17-20
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	17-20
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	11
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1
	26	Ethical approval or approval by research review committee, confirmed with reference number	11

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.