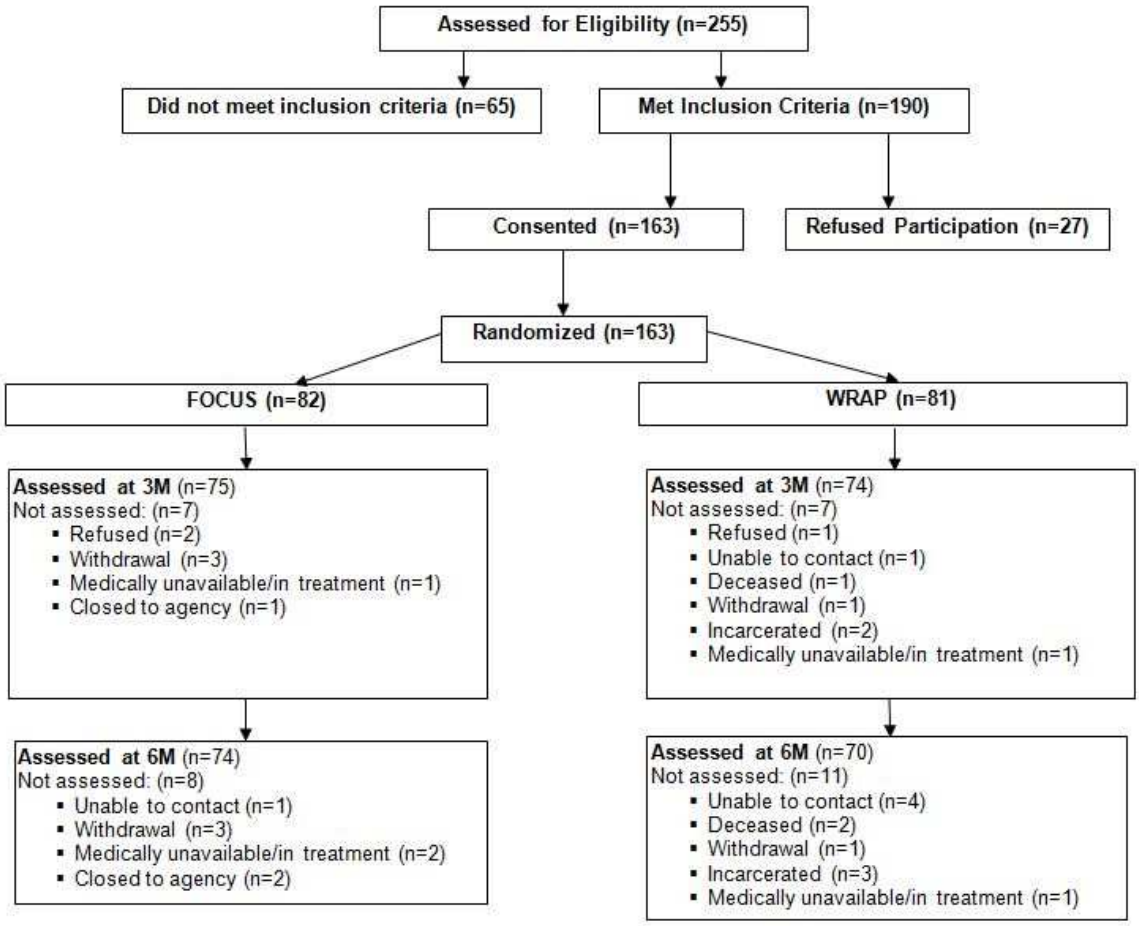
Supplemental Material for:

Mobile Health (mHealth) vs Clinic-Based Group Intervention for People with Serious Mental Illness: A Randomized Controlled Trial

Ben-Zeev et al. 2018

Study Consort Diagram



Complete description of the interventions

FOCUS is a multi-modal, smartphone-delivered intervention for people with serious mental illness. The intervention has three components: a) FOCUS application (app), b) clinician dashboard, and c) mHealth support specialist. The FOCUS app was designed for people who

may have salient psychiatric symptoms, cognitive impairments, and limited education/low literacy. The system includes up to three pre-programmed daily self-assessment prompts as well as on-demand functions that can be accessed 24 hours a day, as long as the battery is charged. Self-management content was adapted from psychosocial intervention strategies targeting five broad domains: *Voices* (i.e., coping with auditory hallucinations via cognitive restructuring, distraction, guided hypothesis testing), *Mood* (i.e., managing depression and anxiety via behavioral activation, relaxation techniques, supportive content), *Sleep* (i.e., sleep hygiene, relaxation, health and wellness psychoeducation), *Social* (i.e., cognitive restructuring of persecutory ideation, anger management, activity scheduling, skills training), and *Medication* (i.e., behavioral tailoring, reminders, psychoeducation). Content can be accessed as either brief Video or Audio clips or sequences of digital screens with written material coupled with visual displays. FOCUS users' responses to daily self-assessments are securely transmitted to a remote server. The information is processed and displayed on an online clinician dashboard with a perpetually updated summary of engagement, module selection, and reported symptom severity over the last 7 days, which is accessible to authorized staff. They were supported throughout the 12-week treatment period by an mHealth support specialist who assisted them in all technical and clinical aspects of the intervention. A licensed clinical psychologist and the chief developer of the FOCUS intervention (DBZ) supervised the mHealth specialist, who met with each FOCUS user individually at the beginning of treatment to provide them with a smartphone with active data plan and FOCUS installed. To ensure technological functionality and reliability, participants were provided with a study device regardless of whether they owned their own smartphone. The mHealth specialist worked with each participant to identify relevant content areas to setup their daily prompts, guided them through a brief tutorial on how to use the phone (e.g., how to receive and make calls, use the touchscreen, set the volume) and engage in the intervention (e.g., responding to prompts, accessing on-demand features, exploring modules). In every subsequent week, the mHealth specialist called FOCUS users to check–in, solve

technical difficulties, and explore how FOCUS strategies could be applied to their personal recovery goals (10-15 minute call). The mHealth specialist reviewed the clinician dashboard to inform these weekly calls. At the final week participants met with the mHealth specialist again to debrief and to return the smartphone.

WRAP is a widely-used group self-management intervention led by trained facilitators with lived experience of mental illness. Sessions follow a sequenced curriculum, and specific group discussion topics and examples draw from the personal experiences of the participants and co-facilitators in attendance. Although each WRAP group is different, the model emphasizes individuals equipping themselves with 'personal wellness tools,' focusing on recovery concepts (e.g., hope, personal responsibility, self-advocacy), language (e.g., person-first recovery language), development of a Wellness Recovery Action Plan (e.g., establishing a daily maintenance plan, identifying and responding to triggers, early warning signs), and encouraging positive thinking (e.g., changing negative thoughts to positive thoughts, building self-esteem, suicide prevention, journaling). Facilitators incorporate these tools into a written plan, which includes daily maintenance, identification of triggers and methods to avoid them, warning signs and response options, and a crisis management plan. WRAP facilitators and Thresholds' Director of Recovery participated in advanced WRAP Facilitator Training provided by trainers from the Copeland Center, the hub for WRAP and lead training authority internationally. Two facilitators led WRAP sessions over 12 weeks, with sessions lasting 90 minutes. After each WRAP session, facilitators met with the Director of Recovery to review activities, plan for the next session, and examine model fidelity to ensure session content adhered to Copeland Center guidelines. Participants who missed a weekly meeting had opportunities for makeup sessions in person or over the phone that same week.

FOCUS and WRAP are similar in that both interventions are recovery-oriented, use an array of empowerment and self-management techniques, involve similar intervention periods, and have empirical findings suggesting they are engaging and beneficial to people with serious

mental illness. The differences between these approaches represent core distinctions between mHealth and clinic-based models of care (i.e., accessed in one's own environment vs. administered in center, largely automated vs. person-delivered, on-demand vs. scheduled).

Complete description of the analytic approach.

Descriptive statistics characterized the sample with respect to demographic and health information at baseline, and t-test and chi-square tests were used (for continuous and categorical variables, respectively) to compare the groups on these variables. We evaluated engagement using chi-square and treatment satisfaction via t-test. For treatment comparisons among clinical outcomes, we used mixed effects models including treatment condition, study time point (i.e., baseline, 3-month/end of treatment, 6-month follow-up), and an interaction term for treatment condition by time. Linear mixed models [47] were fit for all outcomes except PSYRATS, which was modeled via non-linear Poisson hurdle mixed model which estimates a logistic model for probability of a count > 0 (likelihood of experiencing symptoms) as well as a Poisson model for mean symptom ratings if any symptoms were experienced.[48] PSYRATS was modeled in this way because of the skewed nature and zero-inflation (e.g. 64% of individuals had a score of 0 at baseline) observed in this outcome which made linear models inappropriate for this outcome. For primary and secondary clinical outcomes, we were interested in the difference among intervention groups for changes between baseline to end of treatment (i.e., the treatment effect). Treatment effect is tested by the significance of the treatment*time point interaction term for the 3-month/end of treatment time point, using baseline as the reference time point. Secondary comparisons addressed changes from baseline and from end of treatment to the 6-month follow-up, using contrast statements comparing the treatment*time point interaction term. A random individual-level intercept was included in the model to account for repeated observations within individual. We used an intent-to-treat (ITT) analysis including all randomized individuals. We evaluated whether the treatment effect differed by diagnosis

group by including a diagnosis main effect, interactions with time point and treatment condition, and a three-way interaction (diagnosis*time*treatment). Among individuals receiving FOCUS, we examined whether baseline demographic, treatment use, or health information was associated with clinical outcomes. This subgroup analysis was performed via mixed effects models. All analyses were performed using SAS Version 9.4.