Document: CONSORT Clinical Trials Supplement

Official Study Title: Digital, Community-Advised, Social Action Cluster-Randomized Trial to Increase Civic Participation and Social Connection in the US

NCT Number: NCT07013357

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Title and Structured Abstract

Study Identification

See ClinicalTrials.gov, NCT: 07013357. See “Official Title”

Study Description

See ClinicalTrials.gov, NCT: 07013357. See “Brief Summary” and “Detailed Description”.

Open Science

Trial Registration

See ClinicalTrials.gov, NCT: 07013357.

Protocol and Statistical Analysis Plan

The IRB protocol, statistical analysis plan, along with all other referenced documents can be found in the following OSF repository:

https://osf.io/we3k5/overview?view_only=79a840116e794605b7438adec16c5539

Data Sharing

De-identified individual participant data, including survey responses and coded qualitative indicators derived from discussion sessions and self-talk recordings (not the recordings themselves), will be made available after publication of the main trial findings. Shared materials will include the de-identified dataset, the data dictionary, and the statistical code used for the primary analyses.

The facilitator and self-help session manuals, reading materials for the control group, facilitator training materials, as well as fidelity checklists, can be accessed in the OSF Repository (link in "Protocol and Statistical Analysis Plan").

Facilitator assessments, session transcripts, and GROV activity logs will only be shared in fully de-identified and aggregate form, as these materials may contain sensitive or potentially identifying information. Raw transcripts, facilitator notes containing personal details, audio/video files, and platform activity traces will not be shared due to confidentiality protections.

Access to all shareable materials will require a data use agreement to ensure appropriate use. Requests should include a brief description of the proposed research and will be reviewed by the study team for scientific merit, feasibility, and alignment with ethical and privacy commitments. No personal identifiers will be released. Video and audio recordings are not shared due to privacy protections.

Funding and Conflicts of Interest

- Name of funder: Annenberg Endowment of the Division of Communication Science at Annenberg Public Policy Center.
- Type of funding:
    - Direct monetary support
    - Indirect support: personnel, location, devices, and administrative support
- Role of funder:
    - The funder plays no role in any aspect of the trial's design, conduct, analysis, or reporting.

- No financial and other conflicts of interest of the manuscript authors
- No conflicts of interest.

Introduction

Background and Rationale

N/A

Objectives

To evaluate whether participation in the *Community Discussions and Social Participation* intervention improves individual-level primary outcomes compared with a self-help control condition.

Participants

Adults (18+) residing in the United States, recruited online through a U.S. survey sampling company, with access to the internet, Zoom, and online GROV platform (intervention arm only).

Intervention

Three 90-minute virtual facilitated group sessions focused on (1) fostering social connections, (2) setting and achieving physical and mental well-being goals, and (3) pursuing shared community goals, supplemented by the GROV online platform for ongoing peer engagement.

Comparator

Three 90-minute virtual self-help sessions without facilitation or GROV access (given NIH reading materials instead), led by rotating peer discussion leaders using a structured self-help manual.

Primary Outcomes

Physical well-being (continuous), civic participation (binary), new/re-established social connections (binary), and anxiety (continuous).

Timepoint for Primary Outcome

Measured directly after randomization (Baseline Questionnaire) and one-week post-intervention (Immediate Follow-Up Questionnaire).

Benefits

Potential improvements in participants' social connectedness, goal attainment, and community engagement; acquisition of self-help and discussion facilitation skills; and access to supportive social networks.

Harms

Minimal risk, limited to possible discomfort from sensitive group discussions or minor confidentiality concerns in virtual settings. Safeguards include trained facilitators/co-facilitators, breakout options for de-escalation, and post-session referrals when appropriate.

Design Framework

Although not framed within the formal *estimands* framework, the objective aligns with estimating the average causal effect of the intervention versus control.

Methods

Patient and Public Involvement

Patients and members of the public were not involved in the design, conduct, analysis, or reporting of this trial. The intervention was developed by the research team and a Community Advisory Board (CAB) as part of a prior project for rural areas affected by the substance use epidemic and was adapted to a broader context and broader outcomes. The CAB also advised on

this project. Other components of the study (including protocol development, outcome selection, and dissemination plans) were developed by the research team. No patients were involved.

Trial Design

This study is a two-arm, parallel-group randomized controlled trial with an allocation ratio of 1:1. Participants are individually randomized to either the *facilitated community discussion intervention* (experimental group) or the *self-help discussion condition* (control group). The trial follows a **superiority framework**, testing whether the facilitated intervention produces more favorable composite behavioral and well-being outcomes than the self-help condition. Randomization occurs at the individual participant level using a computer-generated allocation sequence.

Changes to Trial Protocol

This project will be registered at ClinicalTrials.gov, NCT: 07013357 and OSF [https://osf.io/we3k5/overview?view_only=79a840116e794605b7438adec16c5539] before the start of recruitment. Any amendments made during the course of the trial will be reflected in updated registry entries, with full disclosure in the registry history and in all reports and publications arising from the trial. Each amendment will be versioned with date-stamping. For each change, we will report in the final manuscript: what was changed, when (relative to recruitment, analysis, or unblinding), why (justification), whether the change was prespecified in the protocol or is post hoc, and its likely impact on trial validity (bias risk, power, interpretability).

Trial Setting

See ClinicalTrials.gov, NCT: 07013357, Contacts and Locations.

Eligibility Criteria

Inclusion Criteria

Adults aged 18 years or older and currently residing in the United States. Participants should also be fluent in English and have access to a stable internet connection and a device capable of running Zoom. Participants must be available to attend three 90-minute virtual group sessions over approximately three weeks and complete baseline and follow-up surveys.

Exclusion Criteria

Individuals under 18 years of age or not residing in the United States will be excluded. Non-English speakers, those without access to Zoom-compatible technology or a private space to participate, and individuals currently enrolled in any other intervention projects conducted by this team will be removed.

Recruitment Methods

Participants are recruited through the online research platform Forthright, using advertisements through direct email or phone invitations. Recruitment materials describe the study as a voluntary opportunity to join virtual group sessions on well-being and community engagement. Eligible individuals sign the informed consent form before randomization.

Intervention and Comparator

Experimental Group (Facilitated Community Discussion Intervention)

Participants assigned to the experimental condition attend three **90-minute virtual sessions** via Zoom, scheduled one week apart. Sessions are led by a trained facilitator and co-

facilitator who guide participants through structured discussions based on the *Community Discussion Manual*. The intervention focuses on:

- Setting and pursuing personal well-being and community engagement goals (e.g., physical and mental health, civic participation, social connection).
- Encouraging mutual support and goal accountability through group reflection and discussion.
- Strengthening participants' sense of social connection, collective efficacy, and engagement.

Between sessions, participants have access to the *Grid for the Reduction of Vulnerability (GROV)* digital platform, which provides opportunities for peer communication. Facilitators receive supervision and fidelity monitoring by senior project staff.

***Comparator Group* (Self-Help Discussion Control)**

Participants assigned to the control condition attend three **self-help 90-minute virtual sessions** following the same schedule as the experimental group. Sessions are guided by a **self-help manual** that includes structured prompts for goal setting and discussion, with no facilitator involvement. A research member moderates the session to address technical issues and provide referrals. One participant from each group is randomly designated as the **discussion leader**, responsible for following the **self-help manual** and maintaining session flow. Control participants do not have access to the GROV platform. However, we will send them brief NIH reading materials on "Health Tips for Adults".

Materials

All the intervention and self-help materials are available on the OSF repository: https://osf.io/we3k5/overview?view_only=79a840116e794605b7438adec16c5539

Fidelity and Adherence

Facilitators are trained using a standardized protocol and participate in ongoing supervision by a clinical psychologist to ensure fidelity. Session recordings are reviewed and scored on fidelity to confirm adherence to the manual and discussion procedures. Attendance and participation are tracked through session logs and platform data.

Tailoring and Modification

Experimental groups' sessions follow fixed structures and overall topics for three sessions, but specific topics vary based on individuals' personalized goal setting during the sessions. Controls sessions are self-run, so topics are fully decided by group members but the instructions by the research team remains the same across groups.

Outcomes

Primary Outcomes (Prespecified)

- Physical well-being goal progress
- Civic participation
- Social connection
- Anxiety

Assessor: Participant self-report via Qualtrics surveys at baseline and immediate follow-up.

Secondary Outcomes (Prespecified)

Prespecified exploratory outcomes include attitudes toward:

- Health
- Civic participation
- Social support
- Problem-solving
- Political participation attitudes
- Political trust

Assessor: Participant self-report via Qualtrics surveys at baseline and immediate follow-up.

Rationale for Outcome Selection: The primary outcomes operationalize the intervention's theory of change—specifically, that facilitated discussions and between-session engagement will result in greater goal progress, civic participation, social connection, and more favorable anxiety outcomes than the self-help discussion sessions. Outcomes are framed within a superiority trial framework.

Exploratory Outcomes

- Social support
- Subjective well-being
- Not scoring questions (text or numeric entry):
    - Physical well-being goal
    - Civic participation
    - Social connection

Assessor: Participant self-report via Qualtrics surveys at baseline and immediate follow-up.

Additional Notes on Measurement

Session fidelity ratings are assessed separately from recordings and are not outcomes.

Harms

We defined adverse events using Penn IRB guidelines (Penn IRB Reportable Events, 2025). Adverse events (AE) may occur within discussion sessions or surveys, and can include complaints of a participant indicating unexpected risks which cannot be resolved by the research team (e.g., reports harassment, etc.), or other event that may present economic or social harm to a subject or may adversely affect the subject's well-being (e.g., private information leaking) that is directly related to the study. Serious Adverse Events (SAE) are defined as when the participant outcome results in death, is life threatening or requires admission to the hospital and warrants an early end to the trial (see Stopping Guidelines).

Systematically Assessed Harm (active/targeted surveillance)

We did not systematically assess harm since the study poses less than minimal risk.

Non-systematically Assessed Harm (passive surveillance)

Assessment of harms will take place throughout the study through non-systematic assessment. During discussion sessions, co-facilitators and facilitators monitor adverse events (AE) in real time according to the criteria defined above. While surveys do not ask about explicit AE behavior such as self-harm or drug use, we will screen participants survey comments and assess for AE (e.g., complaints, discomfort, etc.). Furthermore, we will screen for adverse events through direct messages on GROV (intervention-only) and email contacts.

When any harm is reported through a discussion session, survey, or contact attempt, it will be reported to the PI and clinical supervisor. Research coordinators, who are not blind to the allocated trial group, will file AEs in the "Adverse Events Tracking Log" in an encrypted BOX

folder. We will note participants CGC, Group, Condition, whether the IRB was contacted, and fill out all columns from the NIH Adverse Event template – event severity, relation to the study, classification as AE or SAE (NIH Adverse Event Report Form, 2025). We will use the NIH template to determine how to grade events based on the severity of harm, whether it is related to the study, and whether it classifies as an AE or SAE. The PI will review the sheet after all data collection is complete to ensure honest reporting.

Sample Size

We conducted power analyses assuming comparable effect sizes (i.e., a Cohen's *d* ranging from 0.30 to 0.50) to those seen in a very similar two-arm C-RCT previously conducted by our research team (see Table 1). Based on these analyses, we determined that we would need to recruit, at most, 200 total participants to have adequate power to detect our anticipated intervention effect. If results are not statistically significant, we will consider doing sequential analyses and recruiting additional participants while adjusting the p-value. This will be considered based on practical limitations such as staffing and funding.

Table 1.

Sample Size Estimation Based on a Two-Arm C-RCT with 10 Cohorts

Cohen's *d*	N per arm	N total	Min n per group	Group design effect	Recruit per group	Total recruit
0.3	88	176	9	1.24	10	200
0.4	50	100	5	1.12	6	120
0.5	34	68	4	1.09	5	80

Note. N per arm = analyzable sample size that an individually-randomized trial would need (per arm / total); min n per group (m) = minimum number of analyzable participants that must be in every group (same in both arms); design effect = 1 + (m-1)ρ (the usual cluster design effect); recruit per group = participants to be recruited per group (assuming a 10% attrition rate at the individual level). The estimations are based on a power of ≥ 80%, an alpha level of .05 (two-sided), two parallel arms with 1:1 allocation to 20 groups in total (10 per arm), and an ICC (ρ) = 0.03.

Explanation of any interim analyses and stopping guidelines

Interim Analyses

We will begin conducting interim analyses of the trial data on a weekly basis once the first two cohorts have completed the immediate follow-up assessment. We will use these analyses to assess whether any adjustments to the study protocol or sample size targets are warranted and monitor adverse events.

Stopping Guidelines

This study will be stopped before its completion if any of the following conditions is met:

- The intervention is associated with serious adverse effects that call into question the safety of the intervention.
- Difficulty in study recruitment or retention significantly impacts the ability to evaluate the study endpoints.
- New information becomes available during the trial that necessitates stopping the trial.
- Other situations occur that might warrant stopping the trial.

Randomization

Sequence Generation

A blocked randomization (1:1) procedure will be used. Once twenty eligible participants with overlapping availabilities are identified, they will form a cohort. We will assign each participant a computer-generated-code (CGC) ranging from 0 to 2000 using the Excel RANDBETWEEN function. We will sort participants in ascending CGC order. From the top of the list downwards, we will first assign “Control” and then “Experimental” conditions in alternating order. If participants complete the baseline questionnaire but do not attend any sessions, we will re-randomize them to a future group. If they do not engage with this second group, we will drop them from analyses.

Allocation Concealment Mechanism

The randomization sequence and resulting assignment list will be stored in an encrypted, access-restricted PennBox folder available only to authorized study personnel. Assignment will occur only after cohort formation, and participants will be notified individually by email after group scheduling, ensuring concealment until allocation is finalized.

Implementation

Research coordinators will generate the allocation sequence, assign participants to groups, and distribute schedules and survey links. Facilitators and co-facilitators who conducted sessions do not have access to the randomization list prior to assignment.

Blinding

Trial participants are blinded to study conditions, whereas research personnel, including facilitators and co-facilitators, are not. In the informed consent form, all participants are informed of the same study process: they will partake in group discussion sessions designed to support U.S. adults who wish to become more involved in their communities and set goals. Study length, descriptions, and payment information are identical. Once all study materials are complete, we will send participants a full disclosure of conditions and study objectives.

Statistical Analysis Plan – CDSP C-RCT

The main statistical analyses will examine the intervention effect (i.e., experimental versus control) on the primary, secondary, and exploratory outcomes (see Table 2). These analyses, and all the following unless stated otherwise, will be conducted using the intention-to-treat (ITT) method. That is, all participants who complete at least one session will be included in the analyses in the group to which they were randomized after replacing missing data by using multivariate imputation by chained equations under the missing-at-random assumption. We will perform multi-level modeling with clustered cohorts and report the intra-class correlations (ICC) of the cohort. For each outcome, we will specify all possible random effects models (i.e., random intercept only, random slope only, random intercepts and slopes without their correlations, and random intercepts and slopes with their correlations) and select the best one based on model-fit indices (i.e., AIC, BIC, and the likelihood ratio test). Based on the selected model, we will report the unstandardized estimate (for continuous outcomes) or odds ratio (for binary outcomes) and 95% confidence interval for the intervention effect on a given outcome. We will also use the mean and standard deviation of each condition to compute the effect size (i.e., Cohen's *d*) for each outcome.

The primary outcomes include four targeted behaviors promoted in the intervention: (a) making progress toward a physical well-being goal (continuous), (b) engaging in civic participation (binary), (c) establishing new or old social connections (binary), and (d) decreasing anxiety (continuous). Please see the *Outcomes and Measurement* document on OSF for further details: https://osf.io/we3k5/overview?view_only=79a840116e794605b7438adec16c5539.

The secondary outcomes consist of six potential mediators: attitudes toward civic participation, social connection, health, problem-solving, and political participation; finally, political trust. We will impose no alpha correction/adjustment for multiple outcome comparisons because we have no conjunction hypotheses and these outcomes are not primary outcomes.

For the exploratory outcomes, we will conduct the same mixed-effects model analysis and will re-estimate the model using ordinary least squares analysis if singular fits occur. All results will be interpreted in an exploratory manner, and no adjustments for multiple comparisons will be applied.

In addition to the main analyses, we will also conduct exploratory mediation analyses to test whether the effect of the intervention on the primary outcomes is mediated by effects on the secondary outcomes. We will test the significance of these mediation effects using bootstrapping with 10,000 iterations. Furthermore, we will carry out mediation analyses by using ChatGPT to conduct thematic coding of de-identified session transcripts, self-talk recordings, and GROV interactions to identify key themes and patterns. All large-language-model (LLM) analyses and model identification will use the research team's OpenAI Team API account, which excludes our data from any model-training or fine-tuning pipelines at OpenAI. Specifically, we will use the GPT-4o mini model or a later version. Models will be frozen at major version upgrades and re-tested to ensure performance parity when other models are employed in the analyses. We will

also double-code 5-10% of the qualitative data alongside the ChatGPT annotations to ensure satisfactory inter-rater reliability.

Finally, we will use multi-level modeling to carry out the following sensitivity analyses and assess the robustness of our results: (a) modified ITT analyses (i.e., including those participants who only completed the baseline and did not attend any sessions); (b) per-protocol analyses (i.e., including only participants who completed all three Zoom sessions originally allocated); and (c) analyses including relevant baseline measures, GROV activities, intervention process evaluation, and fidelity assessment as covariates. The sensitivity analyses described here are not exhaustive, and new analyses may be added based on the research team's decision. We will also conduct process analyses by examining whether the number of sessions attended and GROV engagements correlate with the study outcomes in the intervention group.

The thematic coding of qualitative data and LLM analyses will be conducted in Python and R. Other analyses will be conducted using the R statistical software, and we will test the significance of all results at the $\alpha = 0.05$ level.

Table 2.

C-RCT Outcomes

Tier	Construct(s) & Example Items
Primary	• Physical well-being goal • Civic participation • Social connection • Anxiety
Secondary	• Attitudes toward:

	○ Civic participation ○ Social connection ○ Health ○ Problem-solving ○ Political participation • Political trust
Exploratory	• Social support and connection • Subjective well-being

Sections 22-30

Not applicable.

References

Allison, K. R., Patterson, P., Guilbert, D., Noke, M., & Husson, O. (2021). Logging On, Reaching Out, and Getting By: A Review of Self-reported Psychosocial Impacts of Online Peer Support for People Impacted by Cancer. *Proc. ACM Hum.-Comput. Interact.*, *5*(CSCW1), 95:1-95:35. https://doi.org/10.1145/3449169

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