

A systematic review of randomized trials for engaging socially disadvantaged groups in health research: A distillation approach

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Abstract

Research that fails to include sufficient representation from socially disadvantaged groups cannot make strong inferences about those groups. This relative lack of knowledge poses theoretical and clinical problems for health research. More effective community engagement with socially disadvantaged groups is often proposed as a way to increase research engagement. However, community engagement is a heterogeneous construct, including everything from how participants are contacted to whether researchers work with an organization within the community. Further, community engagement efforts vary widely in their effectiveness in recruiting and retaining participants from socially disadvantaged groups. Therefore, some types of community engagement may be more effective than others. We conducted a systematic review of randomized controlled trials attempting to increase recruitment or retention of socially disadvantaged groups. We then applied systematic distillation procedures to examine which components of community engagement interventions were associated with successful recruitment or retention outcomes. Generally, we found research process related variables (e.g. having a systematic contact plan) most frequently differentiated effective vs. ineffective recruitment or retention outcomes. Partial associations between components in effective interventions, including negative associations, were descriptively stronger than partial associations in the ineffective interventions, indicating targeted interventions may be more effective than more generalized interventions. The literature was also relatively sparse and at unclear-to-high-risk for bias. Future pre-registered, research process-oriented, and targeted recruitment and retention interventions may increase the research participation of socially disadvantaged groups in health research.

Keywords: socially disadvantaged, community engagement, recruitment, retention, intervention

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Competing Interests: The first and second authors are under contract to write a self-guided treatment book for stress and other difficulties in adolescents. The first author has received honoraria from universities and conferences in the US to give talks on adolescent depression and open science practices. The fourth author receives fees for consulting to patients during trials of the manualized treatment for child/adolescent mental health problems MATCH. All other authors have no competing interests. None of these interests are directly relevant to the present work but given the broad applicability of this research we have decided to err on the side of disclosure.

Introduction

Research must represent a population to be valid and generalizable (Kagawa-Singer, 2000). For example, researchers found differential relationships between age and brain structure when contrasting an unweighted sample of 3-18 year olds and a sample weighted based on U.S. Census demographic data (LeWinn, Sheridan, Keyes, Hamilton, & McLaughlin, 2017). However, socially disadvantaged populations (e.g. non-white racial groups, low socioeconomic status, LGBTQ+ status) are less likely to be recruited into research (Clancy, 2019; Murthy, Krumholz, & Gross, 2004). One review identified only nine randomized control trials targeting improved research participation among socially disadvantaged groups (Bonevski et al., 2014). Lack of research makes it difficult to discern effective strategies promoting participation.

Studies often report community engagement as fundamental for improving research participation in socially disadvantaged groups. However, many community engagement strategies fail (Bachour et al., 2016; Schutz, 2006), with effectiveness ranging from 1% to 82% (Johnson, Powell-Young, Torres, & Spruill, 2011; UyBico, Pavel, & Gross, 2007). One review identifies community engagement as the least effective strategy for recruiting ethnic minorities into clinical trials (Johnson et al., 2011). Identifying effective community engagement strategies is critical, as ethnic minority participation in research may be falling over time (Duma et al., 2018; Scalici et al., 2015).

Of studies citing community engagement as essential to the study design, most fail to report what “community engagement” entailed (de Vries & Pool, 2017; Enticott et al., 2017). Community engagement ranges from financial incentives to engaging community organizations. Heterogeneity makes it difficult to compare strategy effectiveness.

Studies often attribute lack of trust in researchers or unwillingness to participate as key barriers to recruiting socially disadvantaged populations (Webb, Khubchandani, Striley, & Cottler, 2018). However, meta-analytic evidence indicates ethnic minorities have consent rates equal to or higher than Caucasians if a participant reaches the consent stage (Katz et al., 2006; Wendler et al., 2006). Many studies fail to *invite* individuals who are representative of the population (Wendler et al., 2006). One surgical intervention offered enrollment to 3,823 Caucasians and 16 non-Caucasian individuals (Feit et al., 2000). Identifying effective recruitment and retention strategies could help illuminate whether addressing participant-level or researcher-level variables will best improve research participation in these groups.

To understand what strategies improve socially disadvantaged group participation in health research, we conducted a systematic review of the literature. The present study defined socially disadvantaged groups as socially, culturally, or financially disadvantaged compared to the majority of society, implying environment or social restriction to their opportunities to participate in health research (Bonevski et al., 2014). Interventions targeting increased group participation were broken down into component parts using distillation methodology previously applied to psychotherapy research (Chorpita & Daleiden, 2009; Chorpita, Daleiden, & Weisz, 2005).

Distillation assesses which strategies were associated with improved recruitment and retention within socially disadvantaged groups. Component success was evaluated by contrasting frequencies with which each component appeared in successful, “winning” interventions versus unsuccessful, ineffective interventions. Exploratory analyses examined whether the presence of each individual component was positively or negatively associated with the presence of other components in “winning” versus ineffective interventions.

Methods

With the goal of producing an overview of articles reporting attempts to increase disadvantaged group participation in research, we conducted a systematic search of the literature as described below.

Eligibility Criteria

To determine eligibility, all articles were screened for inclusion. Articles were included if they reported an attempt to increase participation in research or decrease barriers to conducting research within socially disadvantaged groups. Included articles contained a randomized comparison between at least two conditions. Non-randomized studies were excluded. We also excluded studies if the comparison only focused on age and gender groups or focused on increasing access to health care instead of participation in research. Articles mentioning secondary analyses of participation based on disadvantaged group status were excluded. If an abstract described a review of research on disadvantaged group participation in research, the article was excluded. Articles not published in English and duplicates of previous abstracts were excluded.

Database search

To compile articles for screening, we searched MEDLINE, Cinahl, and PsycINFO via EBSCO for disadvantaged group barriers to participation and participation in research. Key terms describing socially disadvantaged groups were used.

Other sources

In order to find additional eligible studies, we screened the titles of articles that cited included studies as well as articles in the reference sections of included studies (ancestry and paternity searches). Review articles, identified during screening, were also hand searched for eligible articles. For PRISMA details, see Figure 1. For details outlining number and types of article exclusions, see Table 1.

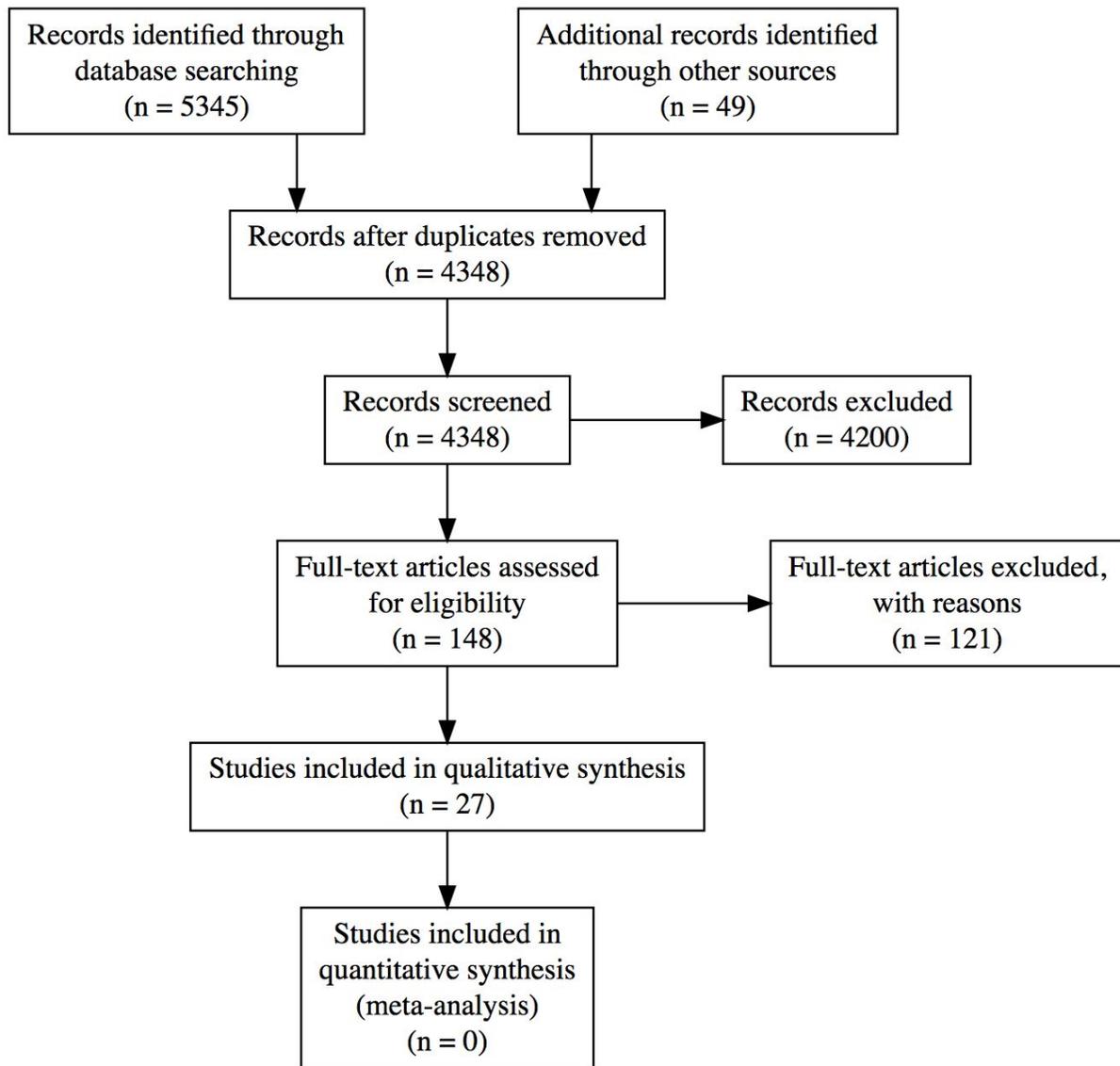


Figure 1. PRISMA Diagram for study eligibility

Exclusion Criteria	Number of Articles Excluded
No mention in abstract of outcomes related to disadvantaged group participation in research or access to healthcare (Code N1)	3,666
Comparison (between-groups, pre-post, quasi-experimental) is focused on increasing access to healthcare, not disadvantaged group participation in research (Code N2)	144
Secondary analyses of recruitment/retention/adherence based on disadvantaged group status are mentioned in abstract of a study where there is a comparison (between-groups, pre-post, quasi-experimental) (Code N3)	60
A review of research on disadvantaged group participation in research (Code N4)	69
Theoretical, qualitative, or commentary research on disadvantaged group participation in research (Code N5)	267
Focused only on age (e.g., adolescents) or gender groups (e.g., females) (Code N6)	38
Not published in English (Code N7)	0
Duplicate of previously coded study (Code N8)	1,046

Table 1. Number and type of exclusions. Exclusion criteria are not mutually exclusive.

Risk of Bias Assessment

We assessed included studies for risk of bias according to Cochrane review criteria (Higgins & Altman, n.d.). All domains of biases were coded as low risk, high risk, or unclear risk. The first source of bias assessed was selection (random sequence generation and allocation concealment). We then assessed performance (blinding of personnel and participants) as a source of bias. The other domains of bias assessed were detection (blinding of outcome assessment), attrition (incomplete outcome data), and reporting (selective reporting).

Component Coding

We first generated component codes based on previous reviews of the literature (Bonevski et al., 2014; Brueton et al., 2013; Duma et al., 2018). We then refined these codes in two stages. We first solicited feedback on our component codes from experts who were part of an interdisciplinary team studying community engagement (Whole Communities, Whole Health at

the University of Texas at Austin). We then iterated our component codes and solicited feedback from a group community members who identify as and/or work with members of socially disadvantaged groups. This iterative process resulted in 23 component codes. These codes broadly cover decreasing logistical difficulty for participants (e.g. having a systematic contact plan), adapting study materials (e.g. shortening materials), working within community structures (e.g. partnering with a community organization), incentives (e.g. financial incentives), and persuasive appeals (e.g. appealing to prosocial behavior). For full list and description of all component codes, see Table 2.

Intervention Component	Definition
Access Promote	Any strategy used to make services convenient and accessible or to proactively enhance participation. This might include availability of on-site child care (“child care”), after-hours scheduling, drop-in appointments (“flexible scheduling”), holding sessions at a local school, the family’s home, or other convenient site (“location”), and transportation to appointments, bus tokens, gas money (“transportation”).
Trust	Any concrete strategies that are explicitly referred to as attempting to build trust with the community. This might include being available at community events, holding public forums, etc. but must explicitly reference these activities as trust-building activities in the text.
Champ	Any direct mention of engaging with an individual in the community who has outsized influence in the community and helped facilitate participation. This is NOT necessarily someone in a traditional position of power (e.g. a school principal or a mayor, see Working with Leaders in the Community category) but someone who is identified in text as particularly important for recruitment and/or retention (e.g. A particular teacher at a school who “champions” the study)
Leader	Any direct mention of engaging with an individual(s) in the community who hold a traditional position of power (e.g. a school principal, a mayor, the leader of a community organization, the head of a clinic) in the text.
Adapt Materials	Any direct mention of modifying study materials or procedures to be more culturally sensitive, culturally competent, or have more cultural humility. For example, adapting recruitment letters to address the history of exploitation of African-Americans by research or providing study materials in multiple languages
Engage Participants Outside	This code only applies to participants already enrolled in a study, not general members of the community. This code involves engaging with the participants outside of attempts at data collection including but not limited to sending thank you cards, birthday cards, and check-ins unrelated to data collection.
Shorten Materials	There is a direct mention of shortening research materials (e.g. consent forms, surveys) as part of the effort to increase community engagement. For example, shortening the survey filled out by participants from 10 pages to 2 pages.
Rationale	Provided Rationale for Why The Research is Being Conducted to the Community, Yes or No? What do we think we’re going to learn? Who are we going to help? Etc.
Intervention Component	Definition (continued)

Branding	Is there direct mention of trying to brand the research being conducted, the study, any incentives provided (e.g. pens, hats), or the research team within the community?
Financial Incentives	Financial Incentives for Participation, Yes or No? Lotteries or drawings count.
Non-Financial Incentives	Non-Financial Incentives for Participation, Yes or No? For example: food, drink, non-study related educational materials, free services.
Community Events	Any explicit mention of attending events in the community to promote the study (e.g. tabling at a community event, presenting at a community event about the study, volunteering in the community)
Time Not Study	Any explicit mention of spending time in the community without directly promoting the study (e.g. providing services, attending neighborhood gatherings without study recruitment materials)
Community Organizations	Any direct mention of working with organizations based in the community (e.g. physically located there, is an organization that advocates for the disadvantaged social group) to engage with the community
Community Share Data	Any direct mention of offering to share the data from the study with the community in summary format or on an individual level or actually doing so
Participant Share Data	Any direct mention of offering to share the data from the study with individual participants in summary format or on an individual level or actually doing so
Personalize	Any direct mention of trying to personalize the research process (e.g. send out handwritten addressed mail instead of typed out addressed mail)
Systematic Contact	Any direct mention of a system to contact and/or keep track of potential or continuing participants (e.g. “we made 3 contacts via phone and 1 by mail”)
Prosocial	Any direct mention of appealing to the desire to help or behave pro-socially while attempting to engage potential or current participants (e.g. Mentioning that participating in research can help us better understand and treat diseases in traditionally under-studied minority populations)

Intervention Component	Definition
Connect Services	Any direct mention of connecting participants or community members with services (e.g. helping connect them to signing up for Medicaid, scheduling doctor’s appointments, etc.)
Near Peers	Any direct mention of using members from the community (broadly defined, could be geographic, sociodemographic, etc.) as people who help with recruitment, retention, collect data, or assist/implement the intervention
Literacy Numeracy	Any direct mention of using techniques to assist members of the community who have differing levels of literacy/numeracy abilities (e.g. adapting materials for

literacy/numeracy reasons, having research staff assist participants in relation to literacy/numeracy)

Other Any other component of the community engagement that doesn't fall under these categories that is explicitly mentioned in the text. Please provide enough detail (e.g. specific page number and quotes from article) so that we can figure out post-hoc if there are any other codes we should include

Table 2. Intervention components and corresponding definitions.

Article Coding

The second and third authors (M.D. and A.M.) independently performed all coding for the systematic review. At the abstract level, the second and third authors double coded all articles for inclusion/exclusion criteria described above. At the full text level, included articles from the abstract screen were double coded for condition randomization; articles that failed to meet this criteria were excluded. All study components were double coded as well, with a Cohen's Kappa of 0.47 on average between the coders, a moderate level of agreement (Landis & Koch, 1977). For all raw component coding data see Appendix A at osf.io/n4f2d/.

After component coding, included articles were double coded for risk of bias. If a risk of bias domain failed to reach 70% agreement, the domain was re-coded by both coders. All coding discrepancies were discussed and resolved in person. If a coding discrepancy could not be resolved between the two coders, the first author (M.M.) resolved the discrepancy. For all raw, study level risk of bias data see Appendix B at osf.io/4qwcf/.

Distillation

After component coding, the articles were processed using the distillation procedure (Chorpita et al., 2005). This procedure involves separating intervention groups by whether they were "winning" interventions or ineffective interventions. The "winning" intervention groups outperformed at least one other group in the same study at increasing recruitment or retention at the $p < .05$ level (Chorpita & Daleiden, 2009). Ineffective interventions were all groups that failed to meet that criteria. We then identified how often each individual component (e.g., having a systematic contact plan) was utilized in "winning" interventions vs. ineffective interventions (Becker et al., 2013). This procedure allows us to identify whether certain components are associated with interventions succeeding more or less often in increasing recruitment or retention of disadvantaged groups. We also conducted descriptive network analyses to visualize how the presence/absence of one component predicts the presence/absence of other components in the same intervention (van Borkulo et al., 2014). For all R code used to process and analyze the data see Appendix C at osf.io/vytqz/.

Results

Study-Level Characteristics

27 studies were included in the analyses. 22 of the interventions targeted recruitment, 4 targeted retention, and 1 targeted both recruitment and retention. 12 studies provided

information on sex for males and females, and 63% of the participants on average were female. Only 4 studies reported age of participants ($M = 32.26$, $SD = 14.54$). 14 studies included enough information to confirm the racial/ethnic composition of the participants. Of those 14 studies, 11 studies included Black participants, 3 studies included Asian participants, 5 studies included Latinx participants, and 3 studies included Caucasian participants who were socially disadvantaged in another category (e.g. minority sexual orientation). See Appendix B at osf.io/4qwcf/ for all demographics data coded at the study level.

Risk of Bias

None of the included studies had low risk for bias in all categories, and this pattern was primarily driven by 63% of the included studies having high risk for selective outcome reporting bias, with the remaining 37% of studies having an unclear, not low, risk for that bias. Out of 164 potential opportunities to assess bias across the 27 studies, there were 94 cases where the risk for bias was unclear based on the study text (57.3%). See Figure 2 for a breakdown in risk of bias by each bias category.

Study	Outcome	Random sequence generation	Allocation concealment	Blinding (participants & personnel)	Incomplete outcome assessment	Selective reporting
Price et al., 1996	recruitment	?	?	?	+	?
Fracasso et al., 2013	recruitment	?	?	?	-	-
Fouad et al., 2014	retention	?	?	-	+	-
Langford et al., 2015	recruitment	?	?	?	+	?
Khosropour et al., 2013	retention	+	+	?	?	?
Brown et al., 2015	recruitment	+	+	+	+	-
Brown et al., 2012	recruitment	?	?	?	?	-
Webb et al., 2010	retention	+	+	?	?	-
Dunlop et al., 2007	recruitment	+	?	-	-	?
Khosropour et al., 2011	recruitment	?	?	?	+	-
Khosropour et al., 2011	retention	?	?	?	+	-
Shea et al., 2008	recruitment	?	?	?	+	?
Jennings et al., 2015	recruitment	+	+	?	?	-
Knoll et al., 2012	recruitment	?	?	?	?	-
Wenzel et al., 2008	recruitment	+	+	?	?	?
Larkey et al., 2002	recruitment	?	?	?	+	-
Ford et al., 2004	recruitment	?	?	?	+	-
Gwadz et al., 2014	recruitment	?	-	-	+	-
Satia et al., 2005	recruitment	?	?	?	?	?
Bell et al., 2005	recruitment	?	?	?	-	-
Nápoles-Springer et al., 2004	recruitment	+	?	?	?	?
Stineman et al., 2011	retention	?	?	?	+	-
Kiernan et al., 2000	recruitment	?	?	?	+	-
Ramirez et al., 2008	recruitment	+	?	?	?	-
Gibson et al., 1999	recruitment	+	?	?	?	-
Maxwell et al., 2009	recruitment	?	?	-	?	-
Martinez-Ebers, 1997	recruitment	?	?	?	?	?
Santoyo-Olsson et al., 2012	recruitment	+	?	?	?	?

Legend
 + = Low risk for bias
 ? = Unclear
 - = High risk for bias

Figure 2. Risk of bias by Cochrane category for each included study.

Distillation Results

Within the included studies, there were 82 total study groups. 86.96% of the components (20/23) were used in at least one group. Three components, Time Not Study (spending time in community without promoting the study), Community Share Data (offering to share study data with community), and Participant Share Data (offering to share study data with individual participants) did not appear in any of groups across all included studies. Of all 23 possible components, Systematic Contact (having a specific system to contact/track participants or potential participants) was the most commonly used component across all study groups (appearing in 71.95% of groups). Next common components were Adapt Materials (modifying study materials or procedures to be more culturally sensitive) and Other (components not falling within one of the pre-specified categories)-both appearing in 46.34% of groups. 19.51% of study groups were successful in outperforming at least one other group, and 82.61% of components were included in at least one successful group. Table 3 reports the exact frequencies with which a particular component was present within successful versus unsuccessful groups.

Intervention Component	Unsuccessful Groups (%)	Successful Groups (%)
Access Promote	17 (25.76)	6 (37.50)
Trust	4 (6.06)	1 (6.25)
Champ	4 (6.06)	3 (18.75)
Leader	3 (4.56)	3 (18.75)
Adapt Materials	28 (42.42)	10 (62.50)
Engage Participants Outside	--	1 (6.25)
Shorten Materials	5 (7.58)	1 (6.25)
Rationale	22 (33.33)	7 (43.75)
Branding	7 (10.61)	2 (12.50)
Financial Incentives	28 (42.42)	9 (56.25)
Non-Financial Incentives	7 (10.61)	3 (18.75)
Community Events	2 (3.03)	2 (12.50)
Time Not Study	--	--
Community Organizations	6 (9.09)	6 (37.50)
Community Share Data	--	--
Participant Share Data	--	--
Personalize	20 (30.30)	2 (12.50)
Systematic Contact	46 (69.70)	13 (81.25)
Prosocial	2 (3.03)	3 (18.75)
Connect Services	3 (4.56)	--
Near Peers	16 (24.24)	6 (37.50)
Literacy Numeracy	9 (13.64)	2 (12.50)
Other	26 (39.39)	12 (75.00)

Discussion

Identifying strategies that increase the representativeness of research participants is essential to increasing the generalizability of research findings. To better understand the specific strategies used in research projects that recruited and/or retained representative participant samples, we conducted a systematic review of the literature. Out of the few studies we found that used randomized controlled experiments to test recruitment and retention strategies, almost all had high or unclear risk of bias. Additionally, strategies previously touted as important to increasing participation, such as increasing trust (Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999; Ford, Havstad, & Davis, 2004; Fracasso et al., 2013; Gwadz et al., 2014), did not differentiate between “winning” and “ineffective” interventions while research process-related strategies (e.g. systematic contact plan) did.

Descriptive networks of relationships between strategies in winning and ineffective interventions indicated stronger associations (primarily negative associations) between components in winning interventions compared to ineffective interventions. In other words, in winning interventions, the presence of one component (e.g. Shortened Materials) meant the very likely absence of certain treatment components (e.g. Prosocial) and the very likely presence of other treatment components (e.g. Access Promote). In ineffective interventions, the presence of one component was not as strongly associated with the presence or absence of other components. Therefore, winning interventions have a more definite, exclusionary composition of components (e.g., if some components are present others won't be) while non-winning interventions have a less certain, more diffuse composition of components. These results imply targeted strategies and interventions may be more effective than approaches taking broad or “kitchen-sink” approaches to increase research participation.

Our results are broadly consistent with previous meta-analytic work indicating lack of effective outreach on the part of researchers may better account for the relative lack of minorities in research than vulnerable groups being less willing to participate (Wendler et al., 2006). The primary differentiating components between winning and ineffective interventions were research process-oriented components such as having a systematic contact plan for participants rather than components oriented toward individual participants such as increasing participants' trust. Certain kinds of interventions focused on research process would be relatively easy to implement for nearly all clinical trials. For example, implementing a systematic contact plan for recruiting and retaining participants in all clinical trials may help researchers increase research engagement among vulnerable groups. Non-systematic contact plans may result in primarily participants who are easiest to recruit and retain, thereby excluding vulnerable groups from the research process.

Appealing to prosocial motives during the community engagement process, or appealing to the participants' desire to help others and their group, appeared to differentiate winning from ineffective interventions. Therefore, focusing more on prosocial motives in recruitment and retention efforts could also be a small change in research process that could reap better

representation for vulnerable groups in research. Though many previous recruitment, retention efforts with vulnerable groups included mention of racial disparities in health outcomes (Weinstein, Lyon, Sandman, & Cuite, 1998), emphasizing disparities rather than potential progress seems to harm rather than increase research participation (Nicholson et al., 2008). Actively appealing to prosocial motives is a relatively small shift in the research process associated with large gains in the likelihood a study will recruit/retain vulnerable groups more effectively.

Other research process-oriented components may be more resource-intensive to implement but are associated with descriptively larger increases in intervention effectiveness. For example, 37.50% of winning interventions worked directly with organizations in the vulnerable community while only 9.09% of the ineffective interventions included this component, the largest percentage difference between winning/ineffective interventions for named components. Coordinating with organizations already working within vulnerable communities may require time and resource investment, but our results indicate there is a clear benefit in terms of vulnerable group recruitment and retention. Adapting materials to make them more appropriate for individuals from vulnerable groups also showed up far more frequently in winning interventions (62.50%) compared to ineffective interventions (42.42%). Adapting research materials well has many hurdles (Flake & Fried, 2019), but effectively doing so could benefit individual participants, a particular study's ability to draw inferences about the population, and the research community as a whole if those adapted materials are made available for others to use.

Consumers of this review may be tempted to take all of the components associated with more winning interventions and create generalized or "kitchen-sink" interventions. However, the descriptive difference in the relationships between components in winning and ineffective interventions indicate that targeted interventions may be more effective than more generalized interventions. The winning interventions had descriptively stronger partial associations between components, including negative relationships, indicating the presence of any one component could make the presence of some other components much more or less likely. On the other hand, ineffective interventions had weaker partial associations, indicating the presence of any one component did not strongly predict whether other components were present or absent. Briefer, less complex, and more targeted interventions may be just as or in some cases more effective across a variety of domains including psychotherapy, working memory training, and health behavior change (Au et al., 2015; Johnson, Scott-Sheldon, & Carey, 2010; Schleider & Weisz, 2017). Combining too many different components in interventions can actually be counterproductive (Schmidt et al., 2000). Therefore, combining all of the components that appear to be more associated with recruitment and/or retention of a representative participant sample may not be an optimal strategy. This systematic distillation recommends certain components that may be best targeted more directly (e.g., identifying existing organizations with whom to partner or adapting materials) .

Still, the number of studies identified for this review suggests that those using experimental methods to test recruitment and retention strategies was relatively limited and all studies

analyzed had unclear or high risk of bias in at least one category. The majority of studies exhibited high risk in the selective reporting category, meaning most studies failed to report all measurements or outcomes. With an unclear to high risk of bias, the reliability of these studies was difficult to ascertain and results from these studies may be misleading since statistically significant results were more likely to be reported. Therefore, all conclusions about the associations of certain components with winning interventions should be tempered by the possibility of inflated incidence of winning interventions due to bias.

In order to decrease risk of reporting bias and improve quality of studies, future interventions designed to improve recruitment or retention should pre-define primary and secondary outcomes of interest (Nosek, Ebersole, DeHaven, & Mellor, 2018). These pre-registrations need not stifle innovation or discourage exploration of data for hypothesis-generating findings (Chambers, Dienes, McIntosh, Rotshtein, & Willmes, 2015). Indeed, the pre-registrations themselves can be flexible, including pre-specified if/then procedures for cleaning and analyzing data rather than rigid, one-size-fits-all rules (Srivastava, 2018). Instead, pre-registration will allow future investigators to better identify which interventions succeeded in targeting their original outcome of interest and even more effectively synthesize which intervention components are most associated with improvements in vulnerable group research participation.

Conclusions

Our review demonstrates the current, randomized controlled literature for increasing research participation among vulnerable groups is relatively sparse and at unclear-to-high risk of bias. The preliminary findings from our systematic distillation indicate research process components, such as having a systematic contact plan, may differentiate winning and ineffective recruitment and/or retention interventions more so than participant-targeted components, such as attempting to increase trust. The relationships between components in winning vs. ineffective interventions appear to indicate that more targeted interventions (i.e., stronger partial associations between components) may be more successful than more generalized interventions (i.e., weaker partial associations between components). More frequent, pre-registered, process oriented, and targeted research participation interventions could improve our ability to generalize the inferences of clinical trials to the general population.

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