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Journal

International Journal of Mental Health and Addiction, 12(4)

ISSN

1557-1874

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Publication Date

2014-08-01

DOI

10.1007/s11469-014-9474-5

Peer reviewed

Int J Ment Health Addiction (2014) 12:420–431
DOI 10.1007/s11469-014-9474-5

Development of an Instrument to Characterize Methodological and Collaborative Factors that May Influence Community-Based Clinician Post-Trial Adoption of Clinical Research Interventions

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Published online: 6 February 2014

Abstract Participation in clinical research trials has been hypothesized to facilitate the adoption of evidence-based practices by community-based substance abuse treatment providers. However, little empirical information is available regarding the methodological and collaborative characteristics of research trials that may affect the chances of adoption. The current paper describes the development of the Survey of Practiced Research Efforts to Aid Dissemination (SPREAD), a standardized instrument designed to measure characteristics of clinical trials that may facilitate adoption. The survey was administered to a sample of 33 community-based research trials from the top four impact factor journals of 2007. Overall, methodological quality was high and levels of collaboration were low, with little involvement of community-based clinic staff in most study related activities. Future research to determine the predictive validity of the SPREAD instrument on post-trial adoption of studies interventions in clinical research is encouraged.

Keywords Substance abuse · Dissemination · Implementation · Adoption · Community-based research

A gap still exists between research and practice in substance abuse treatment, leading to significant efforts to identify factors that may influence dissemination and implementation of evidence-based practices. Community-based clinic participation in research trials may be one viable means of influencing organizational and individual practices and post-trial adoption of evidence-based practices has been highlighted as an innovative method to facilitate the

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diffusion of evidence-based practices (Guydish et al., 2007). While exposure to interventions during clinical research trials may promote adoption of evidence-practices, the methodological characteristics of the clinical trials themselves, and the nature and degree of collaboration between research and community-based clinical staff are all likely to influence whether participation in a clinical trial increases, decreases, or has no impact on post-trial adoption decisions. In some cases, participation in clinical trials may be aversive, and leave community treatment providers with negative impressions of both the research process and the interventions under investigation (Guydish et al., 2005). In other cases, involvement of key community stake holders and interventionists has resulted in positive research experiences and successful post-trial adoption (Ozer et al., 2008). These alternative experiences can lead to differential rates of adoption and missed opportunities to disseminate evidence-based practices through community-based clinical research. The present report is the first empirical effort to measure community-based research trial factors that may influence post-trial adoption through the development of a standardized instrument (Survey of Practiced Research Efforts to Aid Dissemination; SPREAD). We provide normative data for the instrument from a sample of 33 published substance abuse clinical trials. Future trials may use the instrument to determine the predictive validity of methodological factors and collaboration in the adoption of evidence-based practices, with the objective of developing a road map that will guide community-based researchers to conduct clinical trials in a way that will maximize the chances of post-trial adoption.

Evidence from the Clinical Trials Network

Examination of the National Institute on Drug Abuse's Clinical Trials Network (CTN) provides some strong initial evidence regarding post-trial adoption of evidence-based practices. The CTN was designed to facilitate collaborative research between university-based researchers and community-based treatment providers. An objective of this program is to demonstrate effectiveness and external validity of promising interventions and to increase community treatment program adoption of evidence-based medicine principles and practices (Martino et al., 2010; Jessup et al., 2008; Hanson et al. 2002). Through community-based research, the CTN exposes front line treatment providers to interventions with initial evidence of efficacy by providing training and supervision. Consistent with theories on diffusion of innovations (Backer, 1991; Rogers, 2003), participation in such trials may impact crucial adoption processes such as 'exposure' (first hand experience) and 'trialability' (the ability to experiment with; Ducharme et al., 2007).

This CTN paradigm has provided a unique opportunity for empirical testing of hypotheses regarding the influence of research trial characteristics on adoption. Some early work has suggested that participation in the CTN may influence awareness and beliefs regarding evidence-based practice (Arfken et al. 2005). However, the translation of such beliefs into the adoption of tested practices is highly variable. For example, while CTN programs are more likely than non CTN programs to adopt buprenorphine, the same does not hold true for motivational incentives (Ducharme et al., 2007). Similarly, following participation in clinical trials of MATRIX, a manualized treatment for methamphetamine dependence, only one of eight involved community-based treatment programs adopted the intervention (Guydish et al., 2007).

Some insight into these discrepant findings may be offered by the work of Joseph Guydish and colleagues (2006) who, based on structured interviews with varying levels of clinical staff, describe participation in clinical research trials as a potentially negative experience. Based on qualitative interviews with research trial participants at varying levels, Guydish explained the

experience using the metaphor of being visited by an alien 'spaceship' to describe many clinical trials, in which a 'research spaceship' infuses a community-based clinic with resources and protocols, gathers data, and quickly departs, taking with it the training, supervision, and staff necessary to maintain the intervention, and leaving the program with only a vague memory of being visited. If this metaphor is correct, once the research spaceship leaves, there are little resources left to continue evidence-based practices.

Impact of Methodological Factors on Adoption

The methodological characteristics of clinical trials may be associated with adoption. For example, certain methodological factors that increase internal validity may make study findings more compelling to clinical staff, such as having a control group, ensuring the equivalence of groups through procedures such as randomization, and having follow-up assessors who are masked to treatment condition. In addition, the nature of the comparison group may be relevant to clinicians. They may be more persuaded to change behavior by designs that compare tested interventions directly against the standard treatment protocol utilized in their setting, rather than a no-treatment control group. Similarly, clinic staff may be influenced to varying degrees by the nature of measured outcome variables, perhaps attending more to the results of studies that include data they find to be clinically relevant, such as patient satisfaction. Representativeness of the studies sample to the community clinic population as well as robustness factors such as sample size and longest follow-up may also be relevant. While one could argue that high methodological quality might make research findings more compelling to clinic staff, others have suggested such strategies may frustrate providers involved in clinical trials. For example, Obert et al. (2005) argued that "firewalls constructed to protect the integrity of the research may actually hinder and prevent acceptance of the new modality" (pp. 236). To date, the authors of the current investigation are unable to locate any empirical information regarding the impact methodological factors on post-trial adoption. The development of an instrument to measure these factors in community-based research, is a first important step.

Impact of Collaboration on Adoption

Another factor that may influence community-treatment provider adoption of clinical trial interventions is the nature and degree of collaboration that occurred throughout the research process. When participating in clinical trials, increased clinical staff involvement in the planning, execution, and dissemination of the clinical trial might increase the chances of ultimate adoption (Fixsen et al., 2005). In fact, clinician-researcher collaboration in the development and conduct of trials is one of the primary channels through which adoption of evidence-based practices is posited to occur in the CTN (Martino et al., 2010). Collaborative research is defined as the process of bringing both research and real world clinical perspectives together when conceiving, planning, conducting, analyzing, interpreting, or disseminating research (CAPS, 2001). Such an approach to research operates under the assumption that both researchers and clinicians bring unique contributions to the research process regarding the acceptability, sustainability, and relevance of potential interventions, and the methods by which those interventions can best be tested. Collaborative research may increase the quality of investigations by facilitating the development of projects that address clinically relevant problem areas, are replicable within real world settings, and have outcome effects that are valued by patients and clinicians.

In a qualitative outcome follow-up study of two clinics with successful post-trial adoption of MATRIX and motivational enhancement therapy, Guydish and colleagues (2007) determined that several collaborative research trial characteristics showed early promise of facilitating adoption, including developing a plan for adoption early in study development, training senior clinical staff to deliver the intervention, conducting regional trainings, using a local supervision model, providing follow-up training to 'control condition' clinics, and reporting study findings to participating clinics. Although increased collaboration shows some early promise for impacting post-trial adoption of evidence-based practices, little empirical work has been conducted on the topic. To date, there is no standardized method for measuring this factor within the context of clinical research.

The current investigation describes the development of the SPREAD, a standardized instrument designed to measure methodological and collaborative aspects of clinical research that may increase post-trial adoption. The instrument was applied to a sample of community-based alcohol and substance abuse research trials to assess feasibility and develop preliminary normative data.

Method

Participants

The unit of analysis in the current investigation was community-based research trials themselves. Studies were required to 1) examine at least one alcohol, drug, or nicotine intervention condition, 2) report an alcohol, drug, or nicotine use outcome measure, and 3) take place in a community-based clinic or setting, defined as a setting that conducts services outside of the context of clinical research. The sample was obtained by hand searching the 2007 issues of the top 4 impact factor substance abuse journals for studies that meet the inclusion criteria. These journals were *Addiction*, *Drug and Alcohol Dependence*, *Psychology of Addictive Behaviors*, and *Alcoholism*: *Clinical and Experimental Research*. For each included study, information about study characteristics was extracted from manuscripts by trained raters and gathered directly from the primary or corresponding author.

Materials

Developing the SPREAD instrument involved several progressive stages. In stage 1, the researchers conducted a comprehensive literature search to identify methodological and collaborative characteristics of clinical trials hypothesized within the literature to influence post-trial adoption. PubMed and PsycINFO were searched using relevant key terms such as, "community-based research," "adoption," and "dissemination". In addition, researchers searched an annotated bibliography of dissemination publications (Sorensen et al. 2004; http://ctndisseminationlibrary.org/PDF/4.pdf). Based on this search, the researchers developed a list of practices hypothesized within the literature to influence post-trial adoption. Items on the list were transformed into appropriate question/answer formats, including yes/no, Likert, and multiple choice answer options. Two versions of the SPREAD were developed; the $SPREAD_{P,}$ which primarily assesses methodological characteristics of the studies and can be completed by raters with reference to a publication manuscript, and the $SPREAD_{A,}$ which primarily assesses collaboration and can be completed by study authors or others who were closely involved with the implementation of the study. A list of potential item questions was sent to five experts in dissemination experienced in conducting community-based research and the list was iteratively revised based on feedback and pilot testing.

The $SPREAD_P$ was completed by objective raters based on information provided within published manuscripts. The $SPREAD_P$ instrument measures methodological characteristics of studies that may influence adoption. These items were generated from the same literature search described above and also included modified question content from the Methodological Quality Scale (MQS), which has been used in several previous alcohol and substance use related reviews and meta-analyses (Dunn et al., 2001; Hettema et al., 2005; Miller & Wilbourne, 2002). All studies were independently rated by two coders using the $SPREAD_P$, who then met and reconciled differences by referring to the manuscript. $SPREAD_P$ question format included Yes/No ("Did the study include a comparison condition?), multiple choice ("What type of comparison condition was included?: Standard Treatment; No Treatment; Another Intervention), and open-ended formats ("What was the longest follow-up point?").

In addition, the author-based version of the questionnaire was completed by all study authors. The $SPREAD_A$ was administered electronically via Zoomerang software to the authors of manuscripts (www.zoomerang.com). Pre- and post-trial collaboration behaviors were assessed using Yes/No ("Did you gather clinic staff feedback about the study protocol before the trial?") and Likert format (To what degree was administering the study intervention conducted by clinic versus research staff?: Only Clinic Staff; Mostly Clinic Staff; Equally Clinic and Research Staff; Mostly Research Staff; Only Research Staff).

Design and Procedures

$SPREAD_P$. The sample of studies included in the present investigation was identified using the procedures outlined above. For the $SPREAD_P$, the first, third, and forth authors served as raters. Two raters independently coded each article and met to compare ratings. All discrepancies could be resolved conclusively by referring to the study manuscript.

$SPREAD_{A,.}$ For administration of this instrument, the primary or corresponding author was identified based on authorship order or notes within the published manuscript. Author contact information was typically provided directly in the manuscript, but internet searches were required to contact some authors who had moved or changed institutions. Email invitations were sent to the identified author of each study and these included a link to an informed consent and the $SPREAD_A$ instrument. Up to two email reminders were sent to authors who did not complete the survey. In the case of continued non-response, up to three invitations were sent to secondary study authors. In addition, primary or corresponding authors were given the option to identify a co-author or key staff member with high familiarity with the study to participate in their place.

Results

Authors responded to the survey in 33 out of 49 research trials, resulting in a 67.3 % response rate. Most surveys (n=26; 78.8 %) were completed by a study principal investigator, but 21.2 % (n=7) were completed by other key study staff. The basic characteristics of the included study sample are shown in Table 1, including the problem area studied and the intervention of interest. The sample was representative of the diverse target behaviors studied in substance abuse research and the broad range of studied intervention. The sample included 11 drug studies (8 opiate, 1 cocaine, 1 marijuana, and 1 unspecified), 10 alcohol studies, 6 nicotine studies, and 6 studies that targeted a combination of the above. Interventions of interest included group and individual behavioral therapy, pharmacotherapy, acupuncture, monitoring, and sanctions.

Table 1 Articles studied: types of problems and interventions of interest tested

Study	Problem area	Intervention(s) of interest
Anglin et al., 2007	Opiates	Levo-alpha-acetylmethadol (LAAM), methadone maintenance
Baros et al., 2007	Alcohol	Naltrexone
Bell et al., 2007	Opiates	Buprenorphine-naloxone,
Brooner et al., 2007	Opiates	Motivated step care, contingent voucher incentive
Camprodon et al., 2007	Cocaine	High frequency repetitive transcranial magnetic stimulation
Daeppen et al., 2007	Alcohol	Brief intervention
D'Amico et al., 2007	Alcohol and marijuana	Project CHOICE intervention
Ebbert et al., 2007	Nicotine (smokeless tobacco)	High dose nicotine patch
Ebner et al., 2007	Opiates (neonatal withdrawal)	Methadone, slow release oral morphine, buprenorphine
Glover et al., 2007	Nicotine (cigarettes)	Mecamylamine
Godley et al., 2007	Alcohol or drug	Assertive continuing care
Greenfield et al., 2007	Alcohol or drug	Women's recovery group
Kunz et al., 2007	Alcohol (withdrawal)	Ear acupuncture
Jungerman et al., 2007	Marijuana	Motivational interviewing, relapse prevention
Kinlock et al., 2007	Opiates	Methadone maintenance transfer
Krupitsky et al., 2007	Alcohol (withdrawal)	Lamotrigine, memantine, topiramate
Lapham et al., 2007	Alcohol (driving under the influence)	Electronic monitoring and manatory vehicle sales requirements
Lash et al., 2007	Alcohol and drugs	Behavioral continuing care adherence intervention
McCambridge et al., 2007	Opiates	Lofexidine+naloxone, lofexidine
McRobbie et al., 2007	Nicotine (cigarettes)	Rapid smoking
Mihai et al., 2007	Alcohol	Viewing videotapes of delirium tremens
Schwartz et al., 2007	Opiates	Interim methadone maintenance
Sorensen et al., 2007	Opiates	Contingency management
Stasiewicz et al., 2007	Alcohol	Cue exposure in different context
Sutton and Gilbert 2007	Nicotine (cigarettes)	Individually tailored advice letter
Tait et al., 2007	Nicotine (cigarettes)	Brief intervention with telephone support and access to nicotine replacement
Tevyaw et al., 2007	Alcohol	Peer brief motivational intervention
Timko and DeBenedetti 2007	Alcohol and drug	Intensive referral to self help
Toll et al., 2007	Nicotine (cigarettes)	Gain and loss framed cessation messages
Valente et al., 2007	Tobacco, alcohol, drugs	Peer-led Towards No Drug Abuse intervention
White et al., 2007	Alcohol	Brief motivational interview
Winters et al., 2007	Drugs	Brief intervention
Woodall et al., 2007	Alcohol (driving under the influence)	Motivational interviewing

Methodological Factors – $SPREAD_P$

The $SPREAD_P$ was administered to all studies for which authors responded (n=33). Raters achieved near perfect agreement on rated characteristics and all discrepancies were completely resolved by reference to the study manuscript. Table 2 describes the methodological

Table 2 Methodological characteristics of articles studied

Methodological characteristics	
The research included a comparison condition	32/33 (97 %)
Type of comparison condition:	
Standard treatment	13/32 (40.6 %)
No treatment, control	11/32 (34.4 %)
Another intervention	8/32 (25.0 %)
Procedure used to ensure the equivalence of groups	32/33 (97 %)
Follow-up assessors masked to treatment condition.	17/33 (51.5 %)
Longest follow-up point.	*X*=6.4 months (SD=8.9)
Number of participants:	
0–50	5/33 (15.2 %)
51–100	2/33 (6.1 %)
101–200	11/33 (33.3 %)
>200	15/33 (45.5 %)
Representativeness of the sample (1 [not at all] - 5 [very])	*X*=3.8 (SD=.87)
Outcome data type:	
Quantitative instruments	33/33 (100 %)
Qualitative instruments	17/33 (51.5 %)
Objective verification data	11/33 (33.3 %)
Collateral data	6/33 (18.2 %)
Patient satisfaction	16/33 (48.5 %)
Within session process	12/33 (36.4 %)

characteristics of studies. Almost all of the studies (97 %) were randomized controlled trials and comparison groups were fairly evenly distributed between treatment as usual (40.6 %), a no treatment control (34.4 %), and another active treatment (25.5 %). About half of studies (51.5 %) used a procedure to ensure the equivalence of groups. Sample size was generally large, with 33.3 % having between 100–200 participants and 45.5 % of studies exceeding sample sizes of 200. The average follow-up duration was 6.4 months (SD=8.9) and study authors rated the representativeness of the sample to be fairly high (3.8 out of 5; SD=.87). Lastly, a range of outcome data types were used, with all studies endorsing the use of quantitative instruments, and fewer studies reporting the use of qualitative outcome data (51.5 %), collateral report (18.2 %), objective verification (33.3 %), or within session process data (36.4 %).

Collaboration Factors – $SPREAD_A$

Table 3 describes pre-trial and post-trial collaboration factors reported on the $SPREAD_A$ instrument. Overall, pre-trial collaboration efforts occurred more frequently than post-trial collaboration efforts. Educating clinic staff on research methods (69.7 %) was the most commonly endorsed pre-trial collaboration behavior, while providing testimony regarding the intervention from clinicians or patients was the least commonly endorsed (3 %). Among post-trial collaboration behaviors, over half of all study authors reported gathering staff feedback regarding the intervention (51.5 %), while few endorsed offering assistance regarding barriers to adoption (12.1 %).

Table 3 Pre- and post-trial collaboration behaviors of articles studied

Assessed domain	Frequency
Which of following activities were conducted **before** the research trial:	
Provided rationale for intervention based on clinic mission or values	20/33 (60.6 %)
Provided staff testimony	1/33 (3 %)
Provided client testimony	1/33 (3 %)
Observed clinical sessions	11/33 (33.3 %)
Attended staff meetings	20/33 (60.6 %)
Attended supervision sessions	6/33 (18.2 %)
Distributed primary research articles or reviews	11/33 (33.3 %)
Distributed clinically oriented articles	5/33 (15.2 %)
Presented data on research efficacy	12/33 (36.4 %)
Presented clinical practices	16/33 (48.5 %)
Had informal discussions with administrators	21/33 (63.6 %)
Had informal discussions with staff	22/33 (66.7 %)
Researcher provided education to clinic staff on research methods	23/33 (69.7 %)
Study protocol and research methods were pilot tested	15/33 (45.5 %)
Clinic staff feedback was gathered about study protocol and methods	22/33 (66.7 %)
Modifications to study protocol and methods were made based feedback	22/33 (66.7 %)
Intervention was pilot tested	16/33 (48.5 %)
Clinic staff feedback was gathered about the intervention	19/33 (57.6 %)
Modifications to the intervention were made based on feedback	16/33 (48.5 %)
Which of the following took place **after** the research trial:	
Clinic staff feedback was gathered about the intervention	17/33 (51.5 %)
Modifications to the intervention were made based on feedback	6/33 (18.2)
Encouraged adoption by discussing it as an option	15/33 (45.5 %)
Discussed barriers to adoption	12/33 (36.4 %)
Offered assistance regarding barriers to adoption	4/33 (12.1 %)
Left/gave material necessary for adoption	7/33 (21.2 %)
Provided additional training for intervention	8/33 (24.2 %)

The $SPREAD_A$ also assessed the degree to which key study activities were conducted by clinic versus research staff. As seen in Fig. 1, overall study related activities were conducted by mostly or only researchers. This was particularly the case for grant writing, selecting assessment instruments, and designing the protocol and methodology. However, it was less so the case with generating the study idea, making major decisions, and administering the intervention (where research and clinical staff duties were split fairly evenly). The distribution of responsibility for study related product such as the analysis of data, writing and submitting peer reviewed journal articles and other products were also primarily or only completed by research staff.

Discussion

The practices we use to facilitate adoption should be as empirically derived and evidence-based as the clinical interventions we are promoting. Instead of leaving clinicians feeling as if

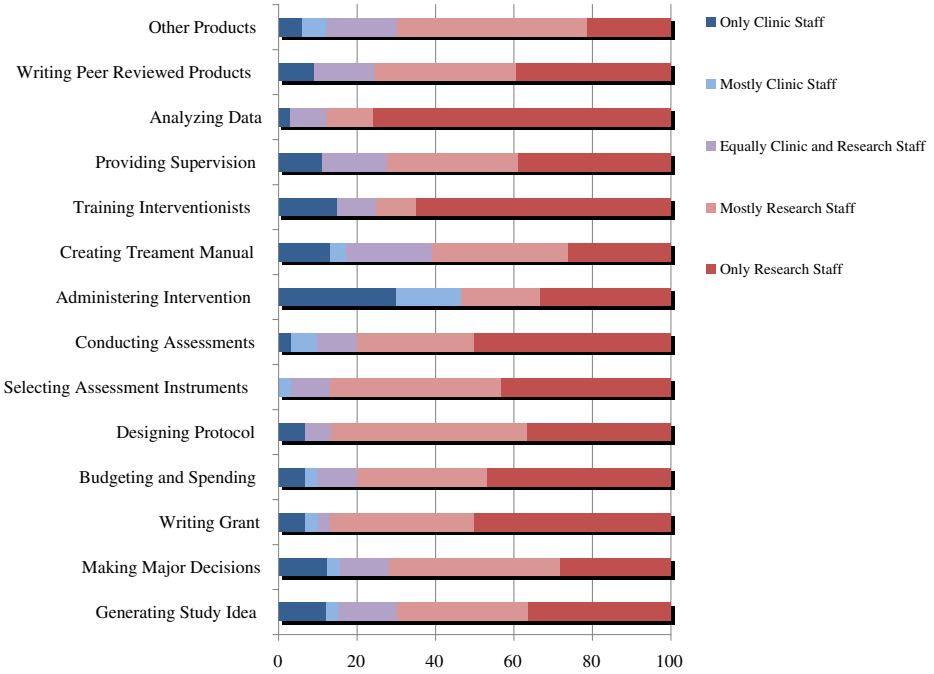

Fig. 1 Distribution of responsibility for study activities

they are being invaded by an alien spaceship, clinical researchers would benefit from an evidence-based road map to guide them in making decisions that will facilitate the adoption of evidence-based practices in the context of their community- based research. In this study, we found that the SPREAD could characterize the methodological and collaboration aspects of a community clinical trial. Moreover, the SPREAD indicates that while methodological quality was generally high, collaboration was generally low. The $SPREAD_P$ and $SPREAD_A$ instruments appear to be feasible tools for empirically measuring factors that may impact post-trial adoption in community-based research. Though evidence-based practices routinely fail to make their way into the hands of front-line clinicians, most information regarding dissemination and implementation techniques is theoretical or anecdotal in nature. Development of instrumentation to describe, predict, and ultimately explain dissemination and implementation processes is needed and the SPREAD instrument may be a tool that will allow us to accomplish these aims in the area of post-trial adoption. The administration of the SPREAD is feasible. We observed variability in responding that increases the predictive validity of the instrument for future trials.

Though the results of the current investigation are promising, several limitations of the trial should be pointed out. First, for the $SPREAD_A$, author perceptions of study related activities were gathered, which may or may not be an accurate reflection of true study events and dynamics. Demand characteristics and other forms of bias could have resulted in authors over-reporting collaboration behaviors. Additionally, community partners were not queried. In this initial study, we intentionally chose to survey researchers because the utility of future SPREAD findings is in affecting future researchers' behavior, and thus their perceptions seem the most relevant. Future versions of the SPREAD may include a community partner survey. Despite potential bias, authors reported surprisingly low rates of collaboration. The

representativeness of the study sample may be another limitation of the current project. Only studies from the top four addiction journals of 2007 were included, and these studies were likely larger and more methodologically sound than the population of community-based research trials that exist. Future research should apply the SPREAD instrument to a more representative sample of studies, particularly if the predictive validity of the instrument is being tested. Having a larger sample of studies would also allow future research to identify the potential moderating impact of type of substance abuse, treatment modality, current evidence-based for the intervention being studied, and stage of research on the relationship between SPREAD factors and adoption.

If a clinical trial brings an evidence-based practice into a clinical setting, the presence of those practices may influence staff and organizational behavior. However, methodological, collaboration, and other factors likely impact the probability and nature of the impact. Glasgow et al. (2003) recommends that methods to study adoption dynamics should be routinely included in efficacy and effectiveness trials. A standardized instrument such as the SPREAD could facilitate such a process. Future prospective research testing the predictive validity of the instrument could facilitate the development of an evidence-based roadmap to facilitate post-trial adoption in clinical research.

Acknowledgments Supported in primarily by Grant 62706/65173 from the Robert Wood Johnson Foundation's Substance Abuse Policy Research Program (PI=James Sorensen; james.sorensen@ucsf.edu), and secondarily by NIH/NIDA Grants P50DA09253 (PI=Sharon Hall; sharon.hall@ucsf.edu) U10DA015815 (PI=James Sorensen), R01DA020781 (PI=Carmen Masson; carmen.masson@ucsf.edu), R21DA020369 (PI=James Sorensen), and T32DA07250 (PI=James Sorensen), and the Robert Wood Johnson Foundation (Dr. Sorensen). While we have benefitted from the support of the funders mentioned here, these represent our views not theirs.

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