INTERVENTIONS TO IMPROVE RETENTION TO CLINICAL TRIALS: A BEHAVIOURAL ANALYSIS OF EFFECTIVE INTERVENTIONS.

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Background
Clinical trials often struggle to retain the number of participants required on which to make valid and reliable assessments about effectiveness of treatments. Several individual randomised comparisons of interventions to improve retention in trials have been shown to be effective. However, the effect across trials is inconsistent (Brueton et al., 2013).
Many of these retention interventions target participants’ behaviour (e.g. returning questionnaires or attending a follow up visit). Although not designed as such, these interventions can be thought of as behaviour change interventions with, for example, returning a questionnaire being the behaviour targeted. By coding the constituent behaviour change components of effective retention interventions, we identified the interventions’ potential ‘active ingredients’ responsible for improvements in retention and will highlight these in this presentation.

Methods
Studies reporting effective (defined by reports testing retention interventions that have been included in a meta-analysis and show evidence of improvements in retention) retention interventions were identified from existing meta-analyses in the literature. Published manuscripts, intervention and control group material, and associated paperwork provided in response to requests to authors were coded into their behaviour change techniques (BCTs) using the BCT taxonomy version 1. Two authors independently coded materials using a standardised coding manual and discussed any disagreements to reach consensus. Data on study characteristics including host trial context, timing, mode of delivery and dosage of retention intervention were recorded.

Findings
Two intervention types were identified as having evidence of improving retention in existing meta-analyses; monetary incentives and text message prompts, with both having their effect on the return of postal questionnaires. No effective intervention was identified to support attendance at face-to-face visits. None of the interventions identified explicitly stated a theoretical rationale for their development or implementation. The BCTs used in ‘monetary incentive’ interventions differed to the control group by use of the BCTs 10.2 material reward (behaviour), 10.8 incentive (outcome), or by 10.10 reward (outcome). Contrastingly, the BCTs identified in ‘text message prompts’ interventions were identical in both the control and intervention groups and differed only in terms of mode of delivery and dosing.

Conclusions
Attending a measurement visit or returning a questionnaire is a behaviour and trialists should be mindful of this when designing retention interventions. Our work in this area provides some of the first evidence of the impact of implicit use of BCTs in retention intervention and highlight their promise for future. This presentation will discuss the use of BCTs in interventions to improve retention in clinical trials, the evidence of their use to date and their potential for future inclusion and evaluation. The promise of theoretical perspectives to inform and improve aspects of trial process and delivery have begun to be
realised. The potential benefits of this approach are likely to outweigh any additional implications and therefore could be considered a key component of trial design decisions.

Start time: 5/23/2018 9:30:00 AM

End time: 5/23/2018 10:30:00 AM

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RETENTION: LESSONS LEARNED AND BEST PRACTICES

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Introduction/Background: Despite its fundamental importance, retention remains among the most challenging aspects in the successful implementation of randomized controlled trials. Barriers to achieving high retention rates may be more pronounced in CTN trials, where participants generally have a current or previous substance use disorder (SUD).

The Center for Clinical Trials Network (CCTN) manages NIDA’s NDAT CTN and works with a Clinical Coordinating Center (CCC), a Data and Statistics Center (both housed at The Emmes Corporation), and 13 research Nodes throughout the United States to conduct multisite substance use treatment studies.

Objective: To disseminate the strategic plan for retention in CTN clinical trials as assembled and distilled from the extensive knowledge of the NDAT CTN Nodes and Clinical Coordinating Center.

Methods: In July 2017, the CCC hosted the NDAT CTN Recruitment and Retention Strategic Planning Meeting at Emmes Corporate headquarters. This daylong meeting brought together a multi-disciplinary focus group with vast experience in clinical trial research with the SUD population. Meeting participants shared tools, media, materials, and experiences across regions and trials, synthesizing them to develop recommendations for general best practices for future studies.

Results/Conclusions: Effective retention must be carefully considered both in the protocol development phase, including budget development, and throughout trial implementation. Efficacious planning prior to study initiation must include an evaluation of the following: eligibility criteria, site-specific barriers, and population-specific barriers including those associated with gender and ethnic/racial minorities. Each inclusion and exclusion criterion should be scrutinized prior to protocol finalization to determine their potential impact on enrollment. Population-specific barriers such as desirability of study interventions/procedures, population comorbid health, psychiatric and social issues, and involvement in the criminal justice system should be considered. Site-specific barriers, including competing research priorities, limited clinical trial experience, and lack of site “buy in”, should inform the site selection processes as well as training and other pre-implementation activities.

Procedures for increasing retention at the site level and monitoring overall progress throughout trial implementation are equally tantamount. Sites will benefit from developing active retention and follow-up plans customized to their participant demographics. Further, teams should develop tracking systems to monitor both retention efforts to meet enrollment goals. For multi-site trials, centralized reports such as those generated on the NDAT CTN website are beneficial. This website includes standardized Trial Progress Reports (TPRs) and Data Status Reports (DSRs) that allow study teams to track retention status from the date of first participant first visit to last participant last visit; additionally, reports may be customized for retention monitoring by summarizing attendance at follow up visits or summarizing participant disposition (e.g., randomized, in active treatment, in follow up).

Overall, planning retention efforts and approaches during study development affords research staff the necessary tools that each site needs to perform retention efforts throughout trial implementation. The
strategic planning group delineated a variety of potential strategies and techniques that can be applied for the successful retention of participants in clinical trials.

Start time: 5/23/2018 9:30:00 AM

End time: 5/23/2018 10:30:00 AM

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Background
There has been more focus on developing successful recruitment strategies in clinical trials than on retaining participants and collecting clinical outcome data. Evidence on factors affecting retention has mostly focused on questionnaire response rates. A survey of UK clinical trials units identified a range of strategies to enhance retention such as participant newsletters and building good relationships with participants.

Methods
A purposive sample of five multi-centre randomised trials was selected from the UK National Institute for Health Technology Assessment portfolio to represent a range of clinical specialities. In-depth interviews were conducted in 2014-2015 with team members from all these trials and three additional senior trial managers to explore strategies for collecting outcome data and retaining participants.

Interview data were analysed thematically using techniques of constant comparison.

Results
Nineteen members of five trials were interviewed, including chief investigators (CI, n = 4), trial managers (n = 5), academic researchers or clinical fellows (n = 5), research nurses (n= 4) and a trial administrator. Some retention strategies such as participant newsletters or reminder letters were well recognised and incorporated in trial protocols. Other strategies were implemented responsively to address retention issues and were less formalised. Interviewees highlighted the importance of fostering positive relationships with participants, for example arranging refreshments or car parking at trial appointments and telephoning unwell participants. However, these strategies took additional time which was not always recognised by funding bodies costing research nurse time. The focus on recruitment targets by national Clinical Research Networks and funders was deemed detrimental to retention which was often overlooked to ensure that the trial reached its recruitment targets. The beliefs and research experience of trial staff also affected their confidence and willingness to collect data, especially around participant withdrawals. Staff conducting follow-up sometimes came into conflict with CIs who expected follow up of everybody whilst staff used their judgement, for example if participants were unwell and stopped data collection regarding this as unacceptable. Clinicians also identified that their patient advocacy role could be conflicted by outcome data collection which they consequently stopped. Small non-monetary incentives were valued by trial staff to legitimise continued contact with participants and thus increase outcome collection.

Conclusion
Trial staff roles and underlying beliefs influence retention practices and combined with an overemphasis on recruitment targets can be detrimental to motivation and retention. There is a need to consider how to train and support staff involved in follow up and highlight the importance of retention to funding bodies and other organisations.
References

Start time: 5/23/2018 9:30:00 AM

End time: 5/23/2018 10:30:00 AM

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UTILIZING A ROBUST AND COMPREHENSIVE LOCATOR FORM AS A RETENTION TOOL IN CLINICAL TRIALS

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Background:
The National Institute on Drug Abuse (NIDA) Clinical Coordinating Center (CCC) and Data and Statistics Center (DSC) support the National Drug Abuse Treatment Clinical Trials Network (NDAT CTN), which evaluates behavioral, pharmacological, and integrated treatment interventions for substance use disorders. These clinical trials routinely enroll participants who may be particularly difficult to find during treatment and follow-up. One tool for increasing retention has been the use of locator forms to obtain contact information from study participants to facilitate locating them. Standard forms collect information such as the participant’s current address, email address, and phone numbers. However, in NDAT CTN studies, which frequently involve participants with unstable living conditions conventional locator forms were not sufficient to reach participants.

Objective:
The goal was to create a comprehensive and robust locator form to more successfully locate participants for their study visits, and to make this tool a focal assessment at screening/baseline.

Methods:
The CCC, DSC, and the study investigative teams have refined the content and collection method of the locator form through numerous iterations, across clinical trials. Some best practices are reviewed, which may aid in locating particularly hard to find participants.

Results/Conclusion:
When a participant falls out of contact with the study team, it is important to use all information available to regain contact and avoid a missed study visit. Use of less traditional information and methodology may be useful. For example, participant “Facebook” profile information (or other social media outlets, such as Twitter) should be collected in the locator form. Similarly, the form could include areas participants would frequent (e.g., medical, social services, support groups, churches, bars) or sleep if unstably housed (e.g., shelters, parks) to aid attempts to locate hard to find participants in the field. Collection of social security and driver’s license numbers are useful and can aid in searches of public records. Information shared during the completion of other study assessments may also inform the collection of locator information. The more robust and inclusive a locator form is, the greater the chance to find a participant and retain them in a study. The collection of locator information should be viewed as an ongoing dialogue with the participant, with a goal of not only obtaining as much information as possible, but obtaining the essential information needed to find that specific participant. Reviewing and updating locator form information at each participant interaction is also important to maintain complete and accurate information. Furthermore, leveraging the data system to enforce collection of information can increase the usefulness of the tool. For CTN studies, flags and requirements were programmed into the electronic data capture system to ensure study team collection of all required information. To ensure confidentiality, data collected on the form was encrypted so that it was only visible to the study team at the site and not transferred into the data files.
Start time: 5/23/2018 9:30:00 AM
End time: 5/23/2018 10:30:00 AM

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