

Recruitment to randomised controlled trials (RCTs) is often difficult and this is particularly the case with adolescents and young adults (AYA), because they require a special approach. This fascinating paper by Trent et al. describes the research methods and preliminary effectiveness of recruitment in their trial, and demonstrates that AYA can effectively be recruited and retained to participate in sexual and reproductive health RCTs.

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RECRUITMENT OF MINORITY ADOLESCENTS AND YOUNG ADULTS INTO RANDOMISED CLINICAL TRIALS: TESTING THE DESIGN OF THE TECHNOLOGY ENHANCED COMMUNITY HEALTH NURSING (TECH-N) PELVIC INFLAMMATORY DISEASE TRIAL

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ABSTRACT

Purpose: Pelvic inflammatory disease (PID) disproportionately affects adolescent and young adult (AYA) females and can negatively impact their short and long-term reproductive health. Few randomised controlled trials (RCTs) have focussed on strategies to improve outpatient adherence, or to reduce reproductive morbidity in this population. This paper describes the research methods and preliminary effectiveness of recruitment, retention, and intervention strategies employed in a novel RCT designed to test a technology-enhanced community health nursing (TECH-N) intervention among urban AYA females with PID.

Methods: AYAs aged 13–25 years were recruited during acute PID visits in outpatient clinics and emergency departments to participate in this trial, approved by an International Review Board. Participants completed an audio-computerised self-interview, provided vaginal specimens, and were randomised to either standard treatment or intervention. Intervention participants received SMS messaging support for 30 days and a community health nurse interventionist performed a home visit with clinical assessment within 5 days of enrolment. All patients received a full course of medications and completed research visits at 14 days (adherence), 30 days, and 90 days with an outreach worker. Sexually transmitted infection testing was performed at the 30 and 90-day visits. Exploratory analyses using descriptive statistics were conducted to examine recruitment, retention, and follow-up data to test the overall design of the intervention.

Results: In the first 48 months, 63.3% of 463 patients were eligible for the study (293), 81.2% of the eligible patients were recruited for the study (N=238). Most participants were African American (95.6%) with a mean age of 18.6 (standard deviation: 2.3). Of those individuals assigned to the TECH-N intervention, 94% completed the nursing visits. All completed visits were within the 5-day window and over 90% of patients in both arms have been retained over the 3-month follow-up period. Biological data suggests a shift in the biological milieu with the predominance of *Chlamydia trachomatis*, *Mycoplasma genitalium*, and *Trichomonas vaginalis* infections.

Conclusions: Preliminary data from the TECH-N study demonstrated that urban, low-income, minority AYA females with PID can effectively be recruited and retained to participate in sexual and reproductive health RCTs with sufficient investment in the design and infrastructure of the study. Community-based sexual health interventions appear to be both feasible and acceptable in this population.

Keywords: Pelvic inflammatory disease (PID), randomised controlled trials (RCTs), adolescents, minority.

INTRODUCTION

Pelvic inflammatory disease (PID) is a serious reproductive health disorder and disease rates remain unacceptably high among minority adolescent and young adult (AYA) females.^{1,2} Each episode of this upper reproductive tract infection, which is usually caused by a sexually transmitted infection (STI), increases the risk of sequelae such as tubal infertility, ectopic pregnancy, and chronic pelvic pain (CPP).³⁻⁸ Care recommendations for PID have shifted from inpatient to the outpatient settings in response to efficacy data from the Pelvic Inflammatory Disease Evaluation and Clinical Health (PEACH) study.⁹ Unfortunately, regardless of the treatment strategy, recent age-stratified analysis from the PEACH data demonstrated that AYAs have high rates of repeat STIs and CPP. Twenty percent of females <25 years old experienced a repeat or persistent STI at 30 days and/or repeat PID over the 7-year follow-up period, with a 5-fold risk of CPP.¹⁰ Furthermore, our local data has shown poor adherence to the 3-day follow-up visit recommended by the Centers for Disease Control and Prevention (CDC), and increased risk for an STI at 90 days. While brief interventions in the acute care setting have had a positive effect, adherence to self-management is problematic.¹¹

Inpatient treatment for PID is expensive without incremental increases in effectiveness compared with outpatient treatment,¹²⁻¹⁵ therefore cost-effective outpatient PID care supports are needed to improve reproductive health outcomes for this vulnerable population.^{10,16,17} Previous work from our group demonstrated that young females perceive significant health-related quality of life reductions and desire more closely monitored care for PID by

clinicians, which was informative for strategically guiding the intervention we advanced herein.^{14,18}

Research has demonstrated that community health nurse (CHN) interventions can increase access to resources, enhance health care utilisation, and promote risk-reducing behaviour.¹⁹⁻²¹ We postulate that integrating a technology component into CHN care would increase appeal to AYAs, given data showing that use of SMS messaging enhances attention paid to medical visits, medication adherence, and health communication.^{22,23} We hypothesised that repackaging the CDC-recommended follow-up visit using a technology-enhanced community health nursing intervention (TECH-N) with integration of an evidence-based STI prevention curriculum and SMS communication would reduce repeat infection by improving adherence to PID treatment and reducing unprotected intercourse, and would be more cost-effective compared with standard care.

We are currently enrolling AYAs diagnosed with PID and randomising them to receive CHN clinical support using a single post-PID face-to-face clinical evaluation and SMS communication support during the 30-day period following diagnosis (intervention group) or standard care (control group). In this paper, we discuss the design and methods of this novel, randomised controlled trial (RCT). We also describe the preliminary 48-month effectiveness of recruitment and retention strategies being employed in this research, designed to reduce recurrent STIs that result in adverse reproductive health outcomes after PID.^{10,17,24}

CONCEPTUAL FRAMEWORK

This work builds on our previous studies with AYA females with PID demonstrating inadequate

interface with the healthcare system and poor adherence to treatment.¹¹ For this work, we employ the integrative model of behavioural prediction²⁵ to frame our approach. Our previous work has allowed us to demonstrate that the distal (demographics) and intermediate (self-efficacy) factors do not sufficiently allow us to predict behaviours. Despite issues with adherence, AYAs express high treatment value and self-efficacy.²⁶ Capitalising on the positive attitudes towards treatment, we are attempting to change behaviour by:

- i) Affirming positive outcome expectations
- ii) Enhancing sexual health skills (e.g. condom use)
- iii) Removing environmental constraints (e.g. transportation).⁹

We employ comprehensive, structured CHN care that includes:

- i) Standardised prevention case-management components
- ii) An effective one-on-one intervention for STI behaviour change^{27,28}
- iii) PID-related health SMS messages as core components of the TECH-N intervention.

METHODS

Study Overview

The TECH-N team is actively enrolling 350 AYAs with mild-to-moderate PID in a 2-arm, single-blinded RCT. Participants are recruited from a large urban academic hospital system located in an STI-prevalent community in the USA. Patients enrolled in Arm 1 (TECH-N intervention group) receive standard care according to the CDC guidelines: a full course of medication, a welcome SMS message followed by daily medication reminders and tri-weekly messages following the 14-day treatment period up to 30 days, and community-based visits by a TECH-N at 3-5, 14, and 30 days following their PID diagnosis. In Arm 2 (control group), patients will also receive standard care treatment including a full course of medications comparable to the intervention group, but are expected to arrange their own 3 to 5-day follow-up, according to standard practice. All participants participate in follow-up interviews at 14, 30, and 90 days. STI testing occurs at the 30 and 90-day study visits, in accordance with timelines for expected disease clearance and reinfection.²⁹

Setting and Participants

The study is being conducted in the Baltimore, Maryland metropolitan area, which currently ranks 10th in the nation for incidence of HIV/AIDs infection²⁹ and 17th for *Chlamydia trachomatis* among its citizens.^{30,31} The Maryland Department of Health and Mental Hygiene has determined that every county is a *C. trachomatis* hotspot and county maps demonstrate that Baltimore is the most densely affected.³¹ Patients are recruited at the time of diagnosis from paediatric and adult emergency departments, general paediatric departments, and AYA outpatient clinics.

Inclusion and Exclusion Criteria

At enrolment, trained research staff perform a detailed review of the study as a part of the informed consent process and patients are screened for eligibility. Inclusion criteria include age 13-25 years, diagnosis of mild-to-moderate PID with a disposition to outpatient treatment, residence in the Baltimore metropolitan area, willingness to give informed consent, and to be randomised. Patients who are pregnant, have a concurrent diagnosis of sexual assault, or are unable to communicate with staff due to cognitive, mental, or language difficulties are ineligible.

Enrolled participants complete an audio computerised assisted self-interview (ACASI) to collect baseline information, and are randomised to the TECH-N or control group using a permuted block design.³² Patients also provide a collection of a vaginal swab for STI testing. After completion of initial study procedures and instruction, patients receive remuneration of \$10 and a 14-day course of medication dispensed by the clinician.

Technology-Enhanced Community-Health Nursing Intervention

The TECH-N intervention includes follow-up by a CHN trained in clinical assessment, indications for physician referral, disease intervention protocols for partner notification and treatment, the CDC guidelines, and the TECH-N protocol. The CHN uses the Sister-to-Sister Teen[®] intervention that has a 20-minute one-on-one module to guide the patient through skill-based risk reduction counselling^{27,28} during home visits 3-5 days after enrolment, consistent with other published PID trials.³³⁻³⁵ Given that only 20% of AYAs adhere to follow-up visits,¹¹ this window proved to be justifiable. Intervention participants are also enrolled in Reify

Health Responsive SMS system® that delivers a welcome message, a prompt to schedule the CHN appointment at 3–5 days, and daily medication reminders for 14 days. After 14 days, the patient also receives positive health reminders for the rest of the month. While 95% of AYAs in our prior research had a cell phone for personal use, many low-income patients have difficulty with monthly maintenance.^{22,23} Participants who are assigned to the intervention and do not have a cell phone are provided one for temporary use.

Control Condition

In the control condition, patients receive standard care per CDC guidelines.³⁶ The institution has integrated standard PID management protocols into usual clinical care as a part of continuous quality improvement protocols.³⁶

Disposition

After completion of informed consent, enrolment procedures, baseline ACASI survey, and specimen collection, the clinician dispenses study-supplied doxycycline 100 mg twice daily for 14 days with or without metronidazole 500 mg twice daily for 14 days and provides discharge instructions for self-care. Clinicians also have access to azithromycin 1 g given orally once a week, to be administered with metronidazole 500 mg taken orally twice daily for 14 days through the study, for the rare patient with doxycycline allergy.^{9,37}

MEASURES

Interview Data

All participants are interviewed by an outreach worker at 14 days post-enrolment to assess residual symptomatology and adherence to the recommendations for self-care.^{9,37} A pill count is performed if the original medication bottle is available at the time of the interview. Patients with ongoing symptoms are discussed with a TECH-N team clinician and referred for care as needed.

In addition to the baseline visit, ACASI is used to collect data at the 30 and 90-day visits. The measures on the baseline survey contain demographics, reproductive and sexual history, PID adherence self-efficacy and perceived barrier scales,^{26,7} social provisions scale,³⁸ and the short-form survey instrument as a measure of health-related quality of life.^{39,40} The 30 and 90-day ACASI surveys capture interim sexual behaviour, condom

use, contraceptive use, interim diagnosis of STIs and pregnancy, and health status.

Technology-Enhanced Community Health Nursing/Community Health Nursing Visit Data

The CHN nurse records contact tracing (e.g. number of contacts to arrange and complete visit) and clinical assessment data including a pain rating scale, abdominal exam, medication usage, supportive care, side effects, activity level, and patient teaching outcomes.

Costs

The costs of administering the intervention is based on hours worked, miles travelled, other supplies, and overhead. The primary cost components for patients in both arms include the initial treatment for PID, follow-up therapy for treatment failure, treatment for recurrent STIs and PID, CPP, ectopic pregnancy, time lost from work/school/household management, travel to PID-related care, and therapy or evaluation for infertility. These data will be used to estimate the direct (medical costs) and indirect (employment, impairment) costs associated with PID for the TECH-N and control arms. Health service utilisation will be derived from the longitudinal interviews, care utilisation data, prescription and over-the-counter medication use, laboratory services, and radiological services. Productivity loss will be derived using the Workplace Productivity and Activity Impairment Questionnaire.^{41,42}

Biological measurements

Participants are asked to provide a self-collected vaginal swab for *Mycoplasma genitalium* and *Trichomonas vaginalis* at baseline to accompany routine testing at the clinical site. Samples to test for *Neisseria gonorrhoeae*, *C. trachomatis*, *T. vaginalis*, and *M. genitalium* are also obtained at 30 and 90 days and processed at the Johns Hopkins University International STD and Respiratory Research Laboratory, Baltimore, Maryland, USA. Vaginal specimens are processed and tested according to the Aptima® Combo 2 (Hologic, Marlborough, Massachusetts, USA) package inserts for *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis*.⁴³ The Aptima urine-based assay was tested using the Gen-Probe transcription mediated amplification research assay in the same manner as for the other Aptima assays. This assay targets *M. genitalium* rRNA for detection in genital specimens.⁴⁴⁻⁴⁸

All participants with positive STI tests are contacted by a research nurse practitioner, notified of their positive test result, and referred for treatment. Positive cases of *N. gonorrhoeae* and *C. trachomatis* are reported to the local health department. The TECH-N encourages partner notification and treatment while providing support and resources to assist all participants.

Incentives

Participants receive a \$10 gift card at enrolment, and \$10 for each completed face-to-face research visit (14, 30, and 90 days) plus an additional \$10 for each STI sample (N=3). AYAs in the TECH-N intervention group do not receive remuneration for the 3 to 5-day clinical care visit because adherence to the CHN clinical visit is a non-incentivised behaviour under study. Participants receive \$5

remuneration for notifying us of changes in cell phone number and/or other contact information.

STATISTICAL ANALYSES

Sample Size

Sample size calculations were driven by the results of our prior research using longitudinal data to examine repeat STIs/PID after an initial diagnosis of PID. At 3 months, the STI positivity rate was 25%²⁴ and thus we assumed this infection rate for the control group. Preliminary data also suggested that we will be able to recruit approximately 175 participants in each arm for a total of 350 participants. We anticipated about 30% attrition over the study period thus each study arm will have an effective sample size of 122.5 participants, for a total of 245 participants.

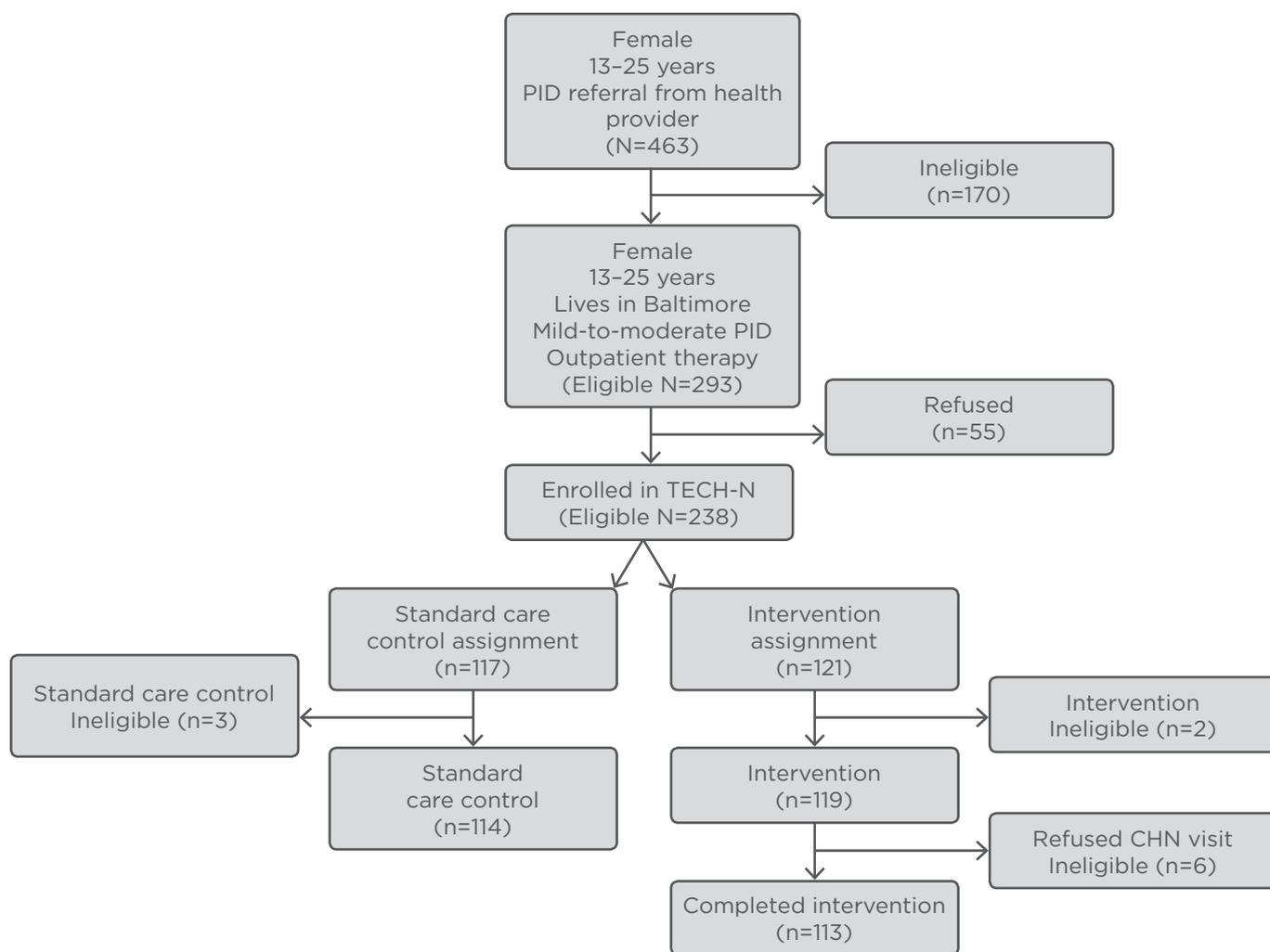


Figure 1: Outcomes of recruitment, randomisation, and retention efforts within the technology-enhanced community-health nursing (TECH-N) study.

PID: pelvic inflammatory disease; TECH-N: technology-enhanced community health nursing; CHN: community health nurse.

Using these assumptions, our power calculations suggest that we will have 80% power to detect a relative risk of 1.66.

Data Analysis

The TECH-N study will compare the effectiveness of the intervention with standard care using an intention-to-treat analysis. We will conduct a logistic regression analysis to: i) determine whether the intervention group showed greater short-term adherence rate compared to the control group and ii) determine whether the intervention group, showed a lower rate of recurrent STIs at 90 days compared to the control group, including potential factors that may affect the difference in rates for both models.

The economic evaluation will examine the net difference in costs between TECH-N and control groups in relation to prevention of: i) recurrent STIs and ii) PID-related complications. The difference in costs will account for the net difference between the outpatient strategies in use of medical services and indirect costs for PID treatment. We will also consider savings in medical-care costs and indirect costs from prevention of the outcome variables. A cost-benefit analysis can be performed comparing the excess costs of TECH-N with the medical care savings and productivity gains from cases averted. We can extend the analysis to a cost-effectiveness evaluation if TECH-N remains more expensive even after accounting for medical care costs and productivity loss averted. In this case, we will measure the dollars spent per case of STI averted over the relevant period.

STUDY UPDATE

In the first 48 months, 293 of 463 patients were eligible for the study (63.3%) and 238 (81.2%) of eligible patients were enrolled (Figure 1). The mean age of participants was 18.6 (standard deviation: 2.3). Most participants were low-income (Medicaid/self-pay [77%]), African American (95.6%), and resided in female-headed households with maternal education level as high school or less. Patients who declined study participation were older (19.8 versus 18.6 years, $p < 0.05$), but otherwise were demographically similar. To date, only 14 of intervention patients (11.6%) required a study cell phone for participation. To date, 19 patients were lost to follow-up, but were demographically indistinct (age, race/ethnicity, insurance status) from those who completed the intervention.

Of those individuals assigned to the TECH-N, 94% completed the intervention. The average number of contacts to execute the CHN visits was 2.46. Almost all eligible participants completed their 14, 30, and 90-day visits (95%, 96%, and 93%, respectively). Mean number of days to complete the 14-day research visit was 1.1 days (SD: 0.55). Baseline laboratory results reveal infection rates that are highest for *C. trachomatis* (26%) and *M. genitalium* (21%), followed by *T. vaginalis* (16%) and *N. gonorrhoeae* (8%). While *M. genitalium* is associated with PID,³³ recent studies have suggested low rates of infection in adolescents⁴⁹ and there is currently no commercial laboratory test for *M. genitalium* to diagnose patients in the USA outside of the research environment. Our data will allow for a longitudinal analysis that may drive differential approaches to testing and therapy.

SUMMARY

PID remains a common reproductive health disorder disproportionately affecting AYA females in urban minority communities. We have demonstrated that using the TECH-N design, AYAs can effectively be recruited during acute PID treatment visits to participate in a longitudinal RCT and can be retained over time. Furthermore, sexual health counselling and clinical follow-up interventions for STI management can be reliably administered in the home by CHNs. While PID is a polymicrobial disorder, the baseline rates of STI positivity suggest a shifting biological milieu in this cohort of AYA females. Moreover, we are reaching the target population of AYAs at high risk for recurrent STIs for intervention.

The strengths of this study include utilisation of evidence-based intervention materials (Sister to-Sister Teen) and innovative communication tools (Reify® SMS) for intervention delivery, and embedding the study in an existing clinical infrastructure. This includes having access to electronic health records to track patient visits during recruitment and the follow-up of results and care outcomes, full-time research staff to work with clinical staff in recruitment sites, and service provision (outreach, STI testing, CHN visits) as a part of the research protocol. As such, TECH-N research staff are viewed as an extension of care.

Staffing of the study has also been a critical component for the success of this programme. In our prior research patients with PID, we

demonstrated high recruitment rates but retained only 70% of the sample.¹¹ Investment in both recruitment and outreach staff has ensured that patients can be effectively tracked in the field without undermining the onsite team. Staff training and team building has resulted in a knowledgeable and high functioning interdisciplinary team. The team is also diverse, but most field staff members are female, further elevating the 'Sister-to-Sister' concept. Our research staff have been described as personable, culturally sensitive, patient, non-judgmental, supportive, committed, and persistent in terms of their execution of the protocol and follow-through with patients in complex social circumstances.

We also recognise the limitations due to the limited generalisability of our sample as a result of the demographics and epidemiology of STIs in Baltimore.²⁹⁻³¹ Despite this, our work has the potential to identify an alternative, cost-conscious

strategy for addressing the observed disparities for AYAs with PID. As with the PEACH trial,³⁴ the confounding effects of race/ethnicity and socioeconomic status are difficult to parse out because the burden of PID is predominately borne by low-income minority women. The PEACH trial group found that younger aged and lower income females were hard to recruit and often excluded.³⁴ We actively seek out these women and attempt to overcome the latter by optimising our design.

Ultimately, this research demonstrates that inclusion of urban, minority AYA females in large community-based sexual health RCTs is highly feasible. It also suggests that adequate investments in developing the research infrastructure are critical for the execution of RCTs designed to reduce PID-related health disparities among vulnerable populations in communities with high STI prevalence.

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