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Conference

Pragmatic Trial Pilots and Designs

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Preventing Maternal Depression, Intimate Partner Violence, and Substance Use during Nurse Home Visiting Augmented with Relationship Education

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Introduction

- ❖ Maternal Depression (MD), Intimate Partner Violence (IPV), Substance Use (SU) are common and co-occurring with profound impacts on mothers and newborns.
- ❖ A few teams addressed them in home visiting (HV).¹⁻⁵
- ❖ As a service delivery model, Nurse Family Partnership (NFP) program is transforming its community practice.⁶
- ❖ Although relationship education (RE)⁷⁻⁸ reduced IPV & distress, HV programs lacks a comprehensive RE model.
- ❖ We examined the effects of NFP augmented with RE to prevent three outcomes & related mechanisms (Figure).

Methods

- ❖ Study Design: Secondary analysis of an RCT of the NFP program in Oregon augmented with IPV screening, referrals, and the *Within My Reach* Curriculum,⁸ delivered by nurses, 2007-2010.^{1,9-10}

- ❖ 238 pregnant mothers were interviewed by research assistants at baseline, 1- and 2-year follow-up, using the Edinburgh Depression Inventory, the Alcohol Use Disorder Identification Test and Drug Abuse Screening Test, and the Revised Conflict Tactics Scale.¹

- ❖ For count outcomes of MD, IPV, and SU, Multilevel Zero-Inflated Negative Binomial Regression Models¹¹ and Mediation Analysis¹² were performed, adjusting for age, race/ethnicity, education, and nativity.

Methods and Results

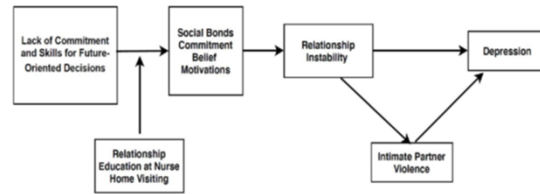


Figure. Proposed mechanisms of change on how relationship education affects intimate partner violence and maternal depression

Table 1. Maternal features and outcomes in the trial in Oregon, 2007 to 2010

Feature	Mean (SD)	SE	95% CI	p-value
Age	29.7 (4.7)	0.03	29.3-4.0	0.56
White	3.8 (3.0%)	0.02	3.2 (2.4%)	0.04**
Hispanic	4.4 (2.7%)	0.02	3.8 (2.4%)	0.03**
U.S.-born	6.6 (5.3%)	0.02	7.1 (5.3%)	0.14
High school graduate	2.6 (2.4%)	0.02	3.1 (2.4%)	0.02**
Annual household income	6.0 (5.8%)	0.02	6.1 (4.7%)	0.13
Parity	2 (2.0%)	0.02	4 (3.9%)	0.07
Partner Relationship	4 (4.9%)	0.02	4 (4.9%)	0.97
Partner Relationship	3.4 (4.7%)	0.02	3.1 (3.8%)	0.27
Maternal depression	0.88 (0.6)	0.01	0.8-0.9	0.15
Intimate partner violence	1.02 (0.8)	0.01	1.0-1.1	0.001**
Substance use	1.0 (0.8)	0.01	1.0-1.1	0.001**

Table 2. Multilevel analyses Note: OR: Odds Ratio, RR: Rate Ratio; 95% CI: Confidence Interval

Effect	Maternal depression		Intimate Partner Violence		Substance Use	
	Lower	Upper	Lower	Upper	Lower	Upper
Logit Submodel			OR		OR	
Intercept			2.14	0.02	2.32	8.06
Wave			0.79	0.46	1.38	0.44**
Intervention			1.28	0.55	2.06	0.69
Wave x Intervention			0.44	0.15	1.27	1.59
Age, years			1.02	0.94	1.11	0.91
Foreign-born vs. U.S.-born			0.51	0.22	1.15	0.47
White vs Others			1.62	0.53	5.00	0.66
Hispanic vs Others			1.90	0.68	5.32	5.80**
High school graduate			1.15	0.61	2.97	0.65
Count Submodel			RR		RR	
Intercept	7.38**	3.41	16.00	2.81	0.73	10.75
Wave	1.00	0.89	1.11	0.81	0.62	1.07
Intervention	0.78	0.60	1.03	0.58	0.37	0.90
Wave x Intervention	1.01	0.87	1.18	0.93	0.69	1.26
Age, years	0.99	0.96	1.02	0.99	0.93	1.04
U.S.-born vs Foreign-born	1.27	0.92	1.75	2.33**	1.36	4.00
White vs Others	0.91	0.65	1.27	0.73	0.42	1.25
Hispanic vs Others	0.81	0.58	1.14	0.62	0.54	1.57
High school graduate	1.01	0.76	1.33	0.98	0.61	1.57
Variance of the intercepts across the participants	2.27**	1.95	2.64	2.28**	1.34	3.86
Covariance between the intercepts and slopes	0.92	0.81	1.04	1.26*	1.04	1.54
Variance of the slopes of waves across participants	1.28**	1.11	1.48	1.15	0.95	1.40
Dispersion parameter	1.22**	1.11	1.35	1.33**	1.09	1.61
Model fit AICc	3640.2			2429.8		1786.1

Note. Among 714 observations across three time points, 82, 87, and 82 for maternal depression, intimate partner violence, and substance use were not included because of missing

Discussion

- ❖ IPV and SU did not differ between two groups at three waves. However, MD differed at 1-year follow-up.
- ❖ The augmented program did not reduce MD, IPV, or SU at the 1- or 2-year follow-up points. It affected MD at 2-year follow-up through IPV as a mediator at 1-year follow-up.
- ❖ Study strengths: Matching statistical modeling with distribution; Limitations: Small sample size, missing data.
- ❖ Large trans-disciplinary studies are needed to perform mediation analyses to delineate mechanisms of change and improve home visiting models to prevent MD, IPV, or SU.

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Preliminary feasibility and effectiveness of a new clinical decision support tool in knee arthroplasty rehabilitation

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BACKGROUND

- TKA rehabilitation is typically generic, despite patients' unique healthcare needs and postoperative goals^{1,2}
- We developed a Clinical Decision Support (CDS) tool to facilitate a more personalized TKA rehabilitation approach

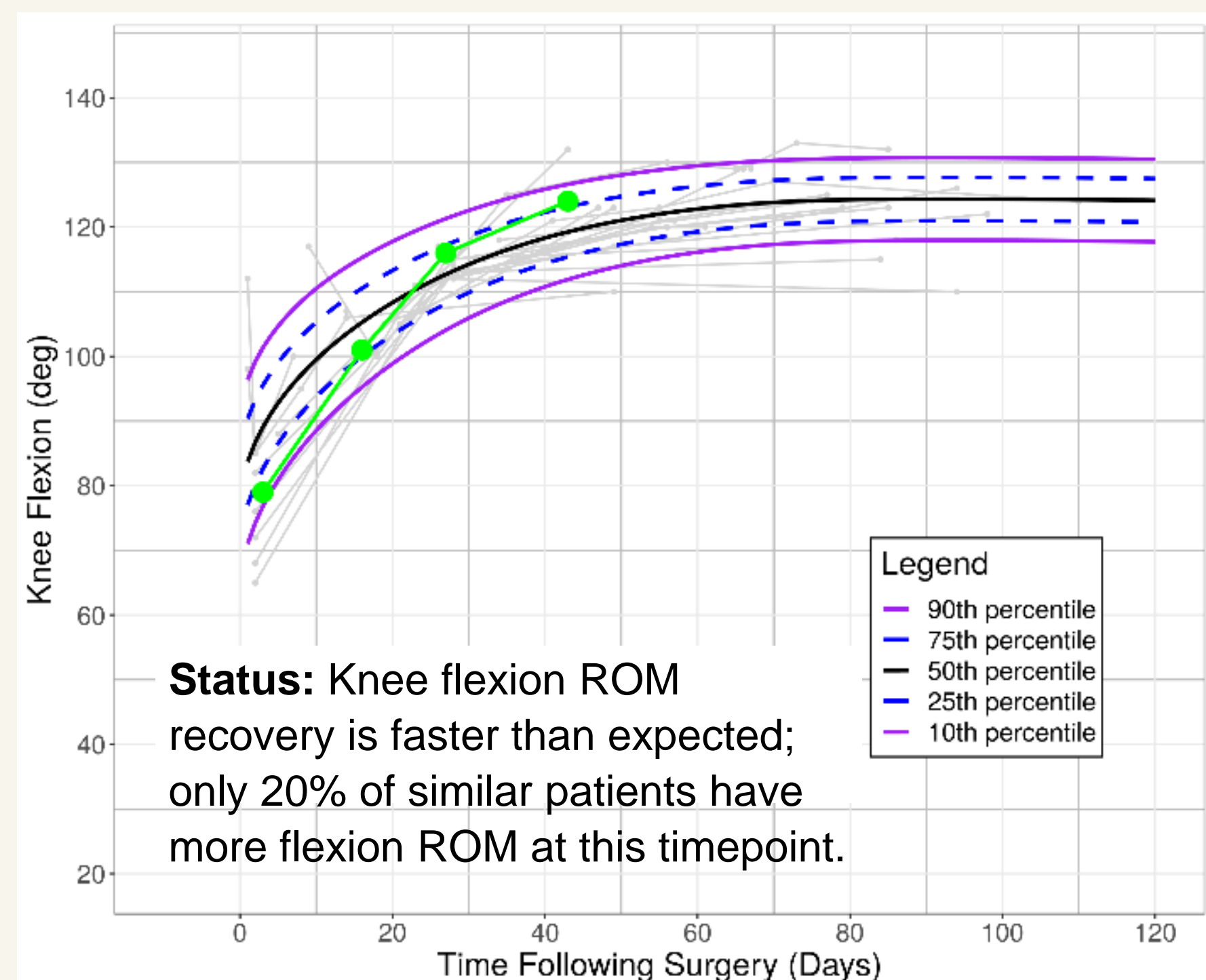
PURPOSE

To examine the CDS tool's preliminary implementation and effectiveness in outpatient TKA rehabilitation

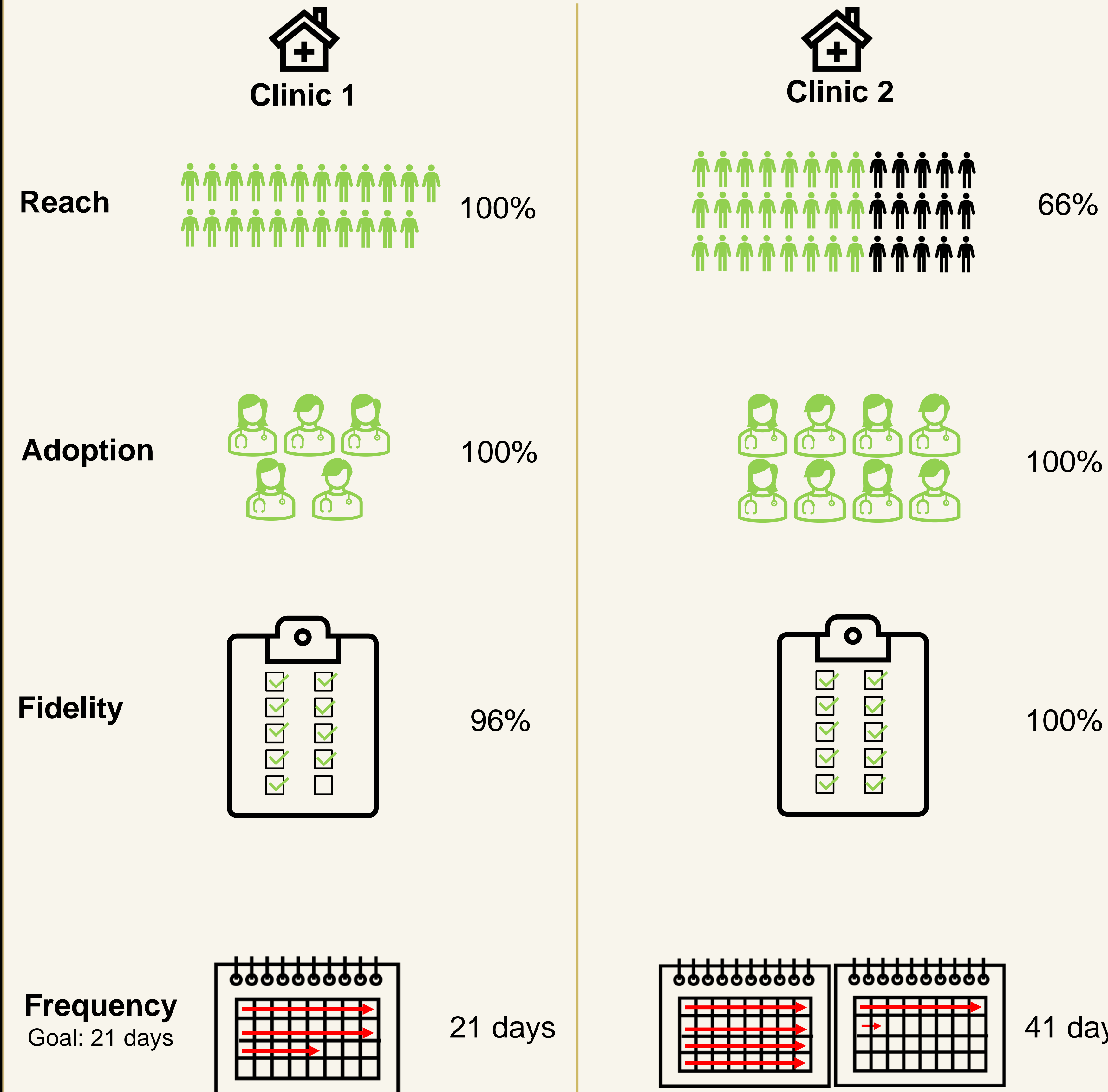
SETTING

Aging by Marie Van den Broeck from NounProject.com

All patients with TKA at two ATI Physical Therapy clinics in the Greenville, SC area



IMPLEMENTATION³



Calendar by Palukx from NounProject.com, Clinic by Pavitra from NounProject.com

EFFECTIVENESS

Patients treated with the CDS tool

- Attended fewer visits
- Reported better function
- Reported greater knowledge

FUTURE DIRECTIONS

- Interviews and surveys with patients, clinicians, and ATI leadership
- Mixed methods analysis of feasibility results
- Refine CDS tool and implementation strategy
- Large scale CDS tool deployment and testing

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An Adaptive Physical Activity Maintenance Intervention for Cancer Survivors

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PHYSICAL ACTIVITY FOR TREATMENT AND PREVENTION LABORATORY

BACKGROUND

- Structured moderate to vigorous physical activity (MVPA) improves many physical and psychosocial health outcomes for cancer survivors. However, less than half of cancer survivors are meeting MVPA guidelines.
- Supervised, theory-based behavior change interventions and programs are effective for increasing MVPA among cancer survivors; however, following an intervention, many survivors return to previously inactive, or insufficiently active lifestyles

Study Objective

To develop a tailored approach to enhance physical activity maintenance in cancer survivors

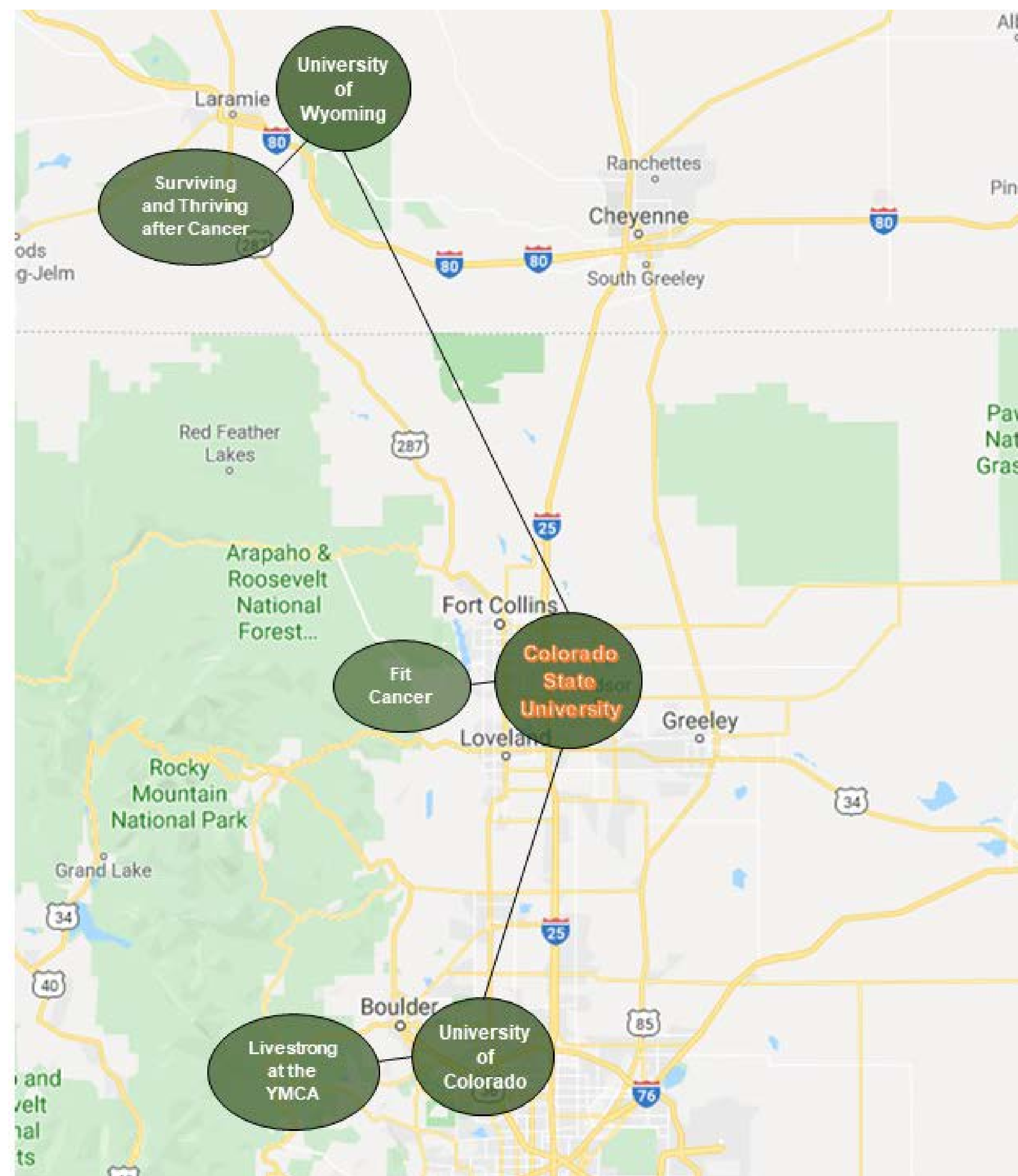
SETTING & POPULATION

Who:

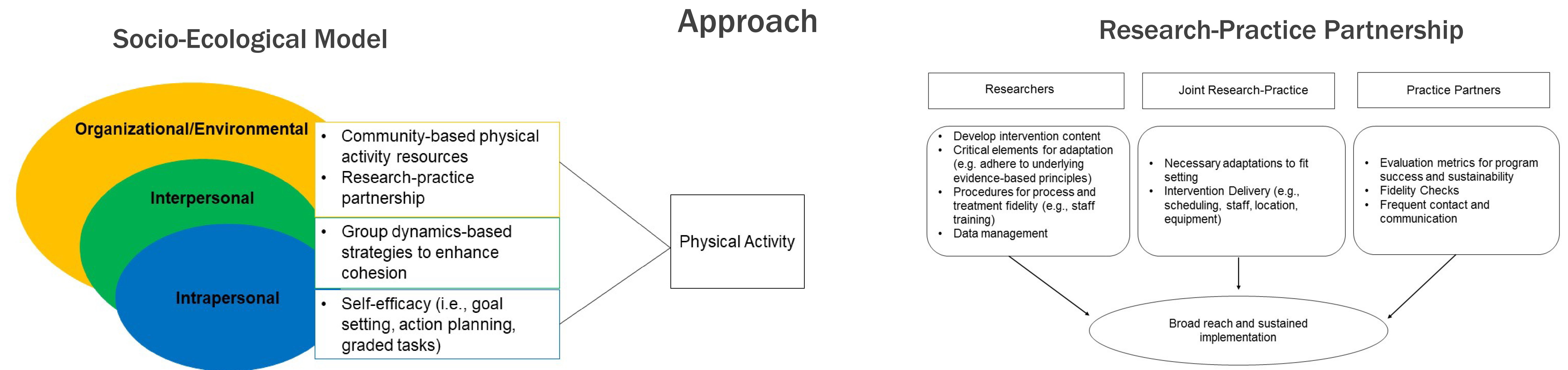
Adult cancer survivors who have completed active treatment within the past five years

Where:

Three community-based exercise oncology programs in Colorado and Wyoming

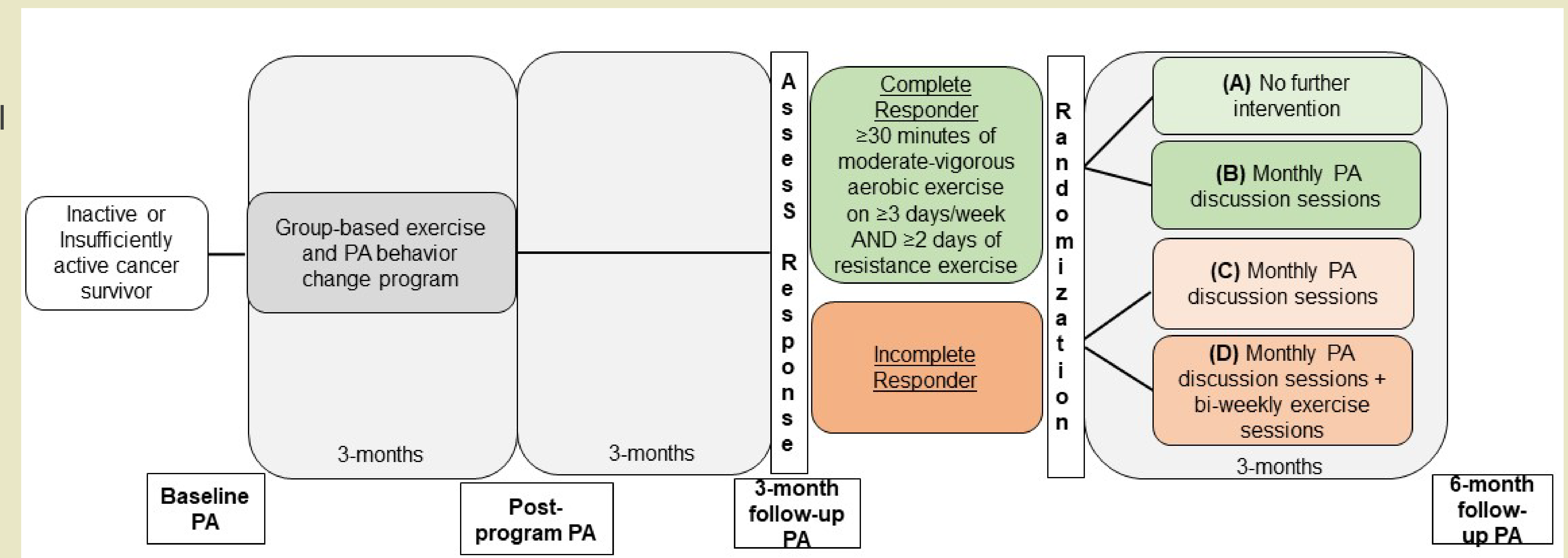


METHODS



Study Design

- Sequential Multiple Assignment Randomized Trial (SMART).
- Fisher's Exact Tests will compare proportion of participants meeting MVPA guidelines at 6-month time-point.



CONCLUSIONS

- This project aims to develop a tailored approach to enhancing PA maintenance, by identifying non-responders and providing them with the additional support necessary to engage in MVPA long-term.
- Findings from this study will prepare our team to test our PA maintenance intervention in a full-scale adaptive trial, powered for efficacy

Funding

National Cancer Institute (1R21CA256656-01A1)



Integrating motivational Interviewing within HIV service organizations: Preliminary findings from a type 3 hybrid trial

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Mark Zehner, Mathew R. Roosa, Kathryn J. Speck, Derek D. Satre, and Steve Martino

Background: As part of the Substance Abuse Treatment to HIV Care (SAT2HIV) Project, Garner and colleagues (2020) found empirical support for the project's Implementation and Sustainment Facilitation (ISF) Strategy, as well as the project's motivational interviewing-based brief intervention (MIBI) for substance use disorders. Building on the SAT2HIV Project and our prior research supporting pay-for-performance (P4P) as an effective (Garner et al., 2011, 2012) and cost-effective (Garner et al., 2018) strategy, the SAT2HIV-II Project was funded (R01DA052294) to test the incremental effectiveness and cost-effectiveness of P4P as a strategy to improve MIBI integration by HIV service organizations (HSOs) and their staff. The current presentation will provide an overview of the SAT2HIV-II Project (i.e., a type 3 hybrid design), as well as present findings from the project's initial cohort.

Setting/Population: U.S.-based HSOs, HSO staff prepared to implement a motivational interviewing-based brief intervention for SUDs, and HSO clients with a comorbid SUD.

Methods: As part of this three-cohort, cluster-randomized, type 3 implementation-effectiveness hybrid trial, an initial cohort of 12 HSOs and their staff ($n = 45$) were randomized to one of two conditions. In the control condition, HSOs and their participating staff received the team-focused ISF Strategy, with the HSO's MIBI staff also receiving a 4-hour online introductory training in motivational interviewing, a 11.5-hour live virtual training workshop in the project's MIBI protocol, ongoing fidelity feedback, and monthly virtual group MIBI consultation meetings with a MIBI expert. In addition to these strategies, MIBI staff working in HSOs randomized to the project's experimental condition had the opportunity to earn P4P bonuses (i.e., \$10 per MIBI implemented and \$10 per MIBI rated as having high-fidelity). Current analyses focused on the time (post-training, mid-implementation, end-of-implementation) by condition interaction for each of the three implementation outcome measures developed by Weiner and colleagues (2017; acceptability, appropriateness, feasibility), as well as a single-item assessing intentions to implement the MIBI (0 = not at all to 6 = highest intentions possible).

Results: Of the three implementation outcome measures examined, only feasibility came close to having a significant interaction between condition and time ($p = .076$), with feasibility ratings decreasing over time for the control condition and increasing over time for the experimental condition. Additionally, a significant ($p < .05$) interaction was found for intentions to implement, with the control condition decreasing over time and the experimental condition decreasing between post-training and mid-implementation, but then increasing between mid-implementation and end-of-implementation.

Conclusion: Consistent with prior research (Garner et al., 2011), P4P significantly increased implementation intentions.

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Facilitating the Research-to-Practice Pipeline through Partnerships: Transitioning a New Peripartum Depression Treatment into the Community

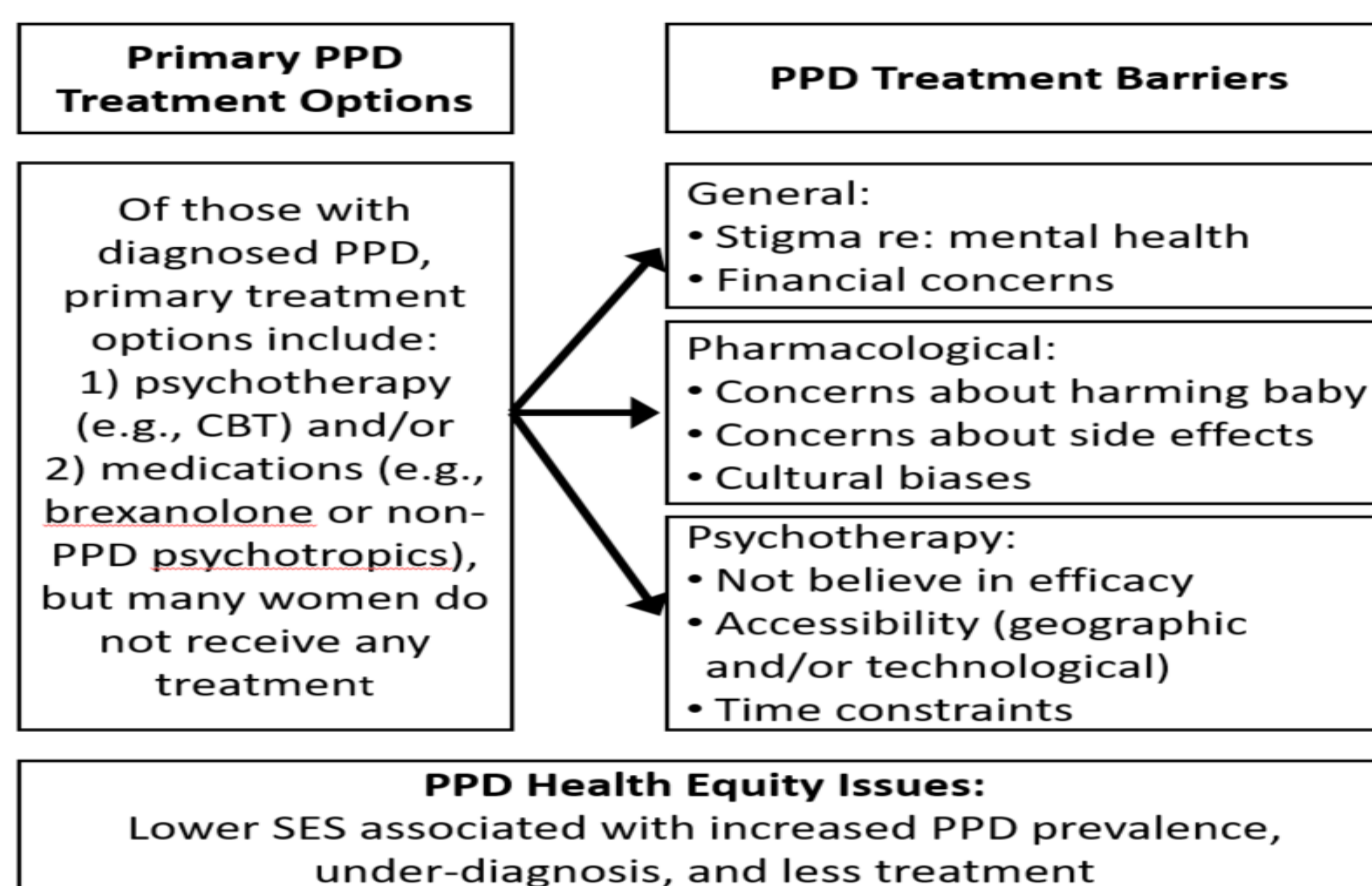
David Sommerfeld¹, Sarah Baldwin², Stacey Annand², Teresa Kang³, Amanda Farr¹, & Barbara Parry¹

¹ University of California, San Diego (UC San Diego); ² Vista Hill, Accessible Depression and Anxiety Peripartum Treatment (ADAPT) Program; ³ County of San Diego, Health and Human Services Agency, Behavioral Health Services (BHS)



BACKGROUND

- Peripartum depression (PPD) is more serious and long-lasting than the “baby blues” and affects 15-20% of women during pregnancy or following birth.
- Untreated PPD can have significant negative effects on the physical and mental health of both mothers and children, including increased mortality risks.
- Many barriers exist to receiving appropriate care.



SLEEP AND LIGHT INTERVENTION (SALI)

- SALI is a newly developed therapeutic approach by Dr. Parry shown to treat PPD in research contexts.
- For women with PPD, SALI works by resetting the frequently misaligned circadian rhythms.
- This is accomplished through one night of adjusted sleep timing and duration (i.e., 4-hours of sleep shifted earlier or later) and two weeks of utilizing a bright white light for 30 minutes/day.
- The specific timing for the sleep and light components of SALI is determined by whether the woman is pregnant or postpartum.
- Key advantages of SALI include:
 - Rapid-acting (i.e., improvements within a week)
 - Short duration/low burden
 - Non-pharmacological
 - Can be completed at home
 - Low/no cost
 - Can be stand-alone or adjunctive to other care

PRAGMATIC RESEARCH THROUGH COMM. PARTNERSHIP

To move SALI from academic research settings to community practice, we utilized existing community partnerships. With support and approval from our partners, we integrated SALI into the previously established community-based Accessible Depression and Anxiety Peripartum Treatment (ADAPT) program to examine SALI effectiveness and implementation-related outcomes. Partners included:

- 1. County of San Diego, BHS**
 - BHS provided funding, initial design, and leadership for the ADAPT program, which is a CA Mental Health Services Act “Innovation” pilot program.
- 2. Vista Hill, ADAPT Program**
 - ADAPT services are provided through Vista Hill, a local nonprofit organization. ADAPT provides PPD treatment and support services to low-income persons experiencing.
- 3. UC San Diego**
 - UC San Diego investigators included implementation science and PPD subject matter experts to conduct the ADAPT outcome and process evaluation.

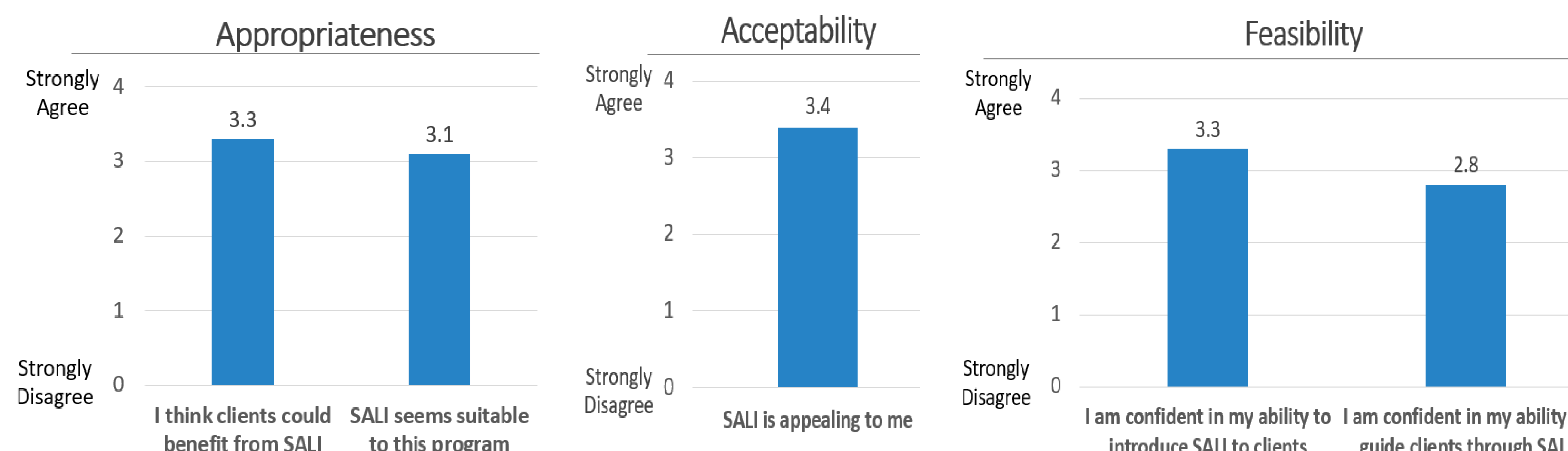
IMPLEMENTATION-RELATED STUDY AIMS

The selection of implementation-related study aims was guided by the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework. Quantitative and qualitative data were collected to assess the following aims:

- 1. Develop and implement tools to train clinicians how to administer SALI.**
- 2. Assess clinician-SALI “fit” (i.e., feasibility, appropriateness, and acceptability).**
- 3. Assess client-SALI “fit” (i.e., feasibility, appropriateness, and acceptability).**
- 4. Develop and implement SALI clinician fidelity rating tools.**

PRELIMINARY FINDINGS FROM ONGOING STUDY

The UCSD team developed and conducted remote (due to COVID) didactic training sessions with ADAPT staff and prepared educational handouts and guidelines for administering SALI with their clients. At the end of the training, ADAPT staff completed a survey (n=11) and indicated their perceptions of SALI as reported in the following charts:



The results indicated that based on the SALI training, clinicians perceived SALI to be appropriate for their clients, of interest/acceptable to the clinician, and generally considered feasible to deliver, although additional support may be needed to increase confidence administering SALI.

PRELIMINARY FINDINGS (CONT'D)

Participation in SALI has been lower than expected (it is an optional treatment with a separate consenting process). To date, less than five ADAPT clients have enrolled in SALI. Initial feedback regarding reasons why ADAPT clients may be hesitant to try SALI suggest that the sleep and light interventions may be perceived as unusual, with some particular concerns about the one night of adjusting sleep.

All the ADAPT clients who started SALI: 1) successfully completed the intervention, 2) reported improvements in mood and/or sleep, and 3) indicated that the intervention was not difficult to complete.

The clinicians involved in administering SALI have also indicated that the SALI was not difficult to administer.

ADAPT clinicians have also requested that SALI materials be developed for use with mono-lingual Spanish speakers (currently in process).

CONCLUSIONS

- Trusting, supportive partnerships with local stakeholders such as community-based service providers and government help facilitate the research-to-practice pipeline. These relationships allow intervention developers to design and adapt treatment approaches that will be effective in “real world” service settings.
- SALI exhibits much promise and is viewed as appropriate, acceptable, and feasible for community use with low-income populations, which can help address disparities.
- However, more work is required to understand the initial hesitancy of clients so that appropriate information and supports can be provided to address potential concerns.

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