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School-based health centers addressing health equity for LGBTQ+ patients

Submission date	**Recruitment status**	[_] Prospectively registered
18/09/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/09/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/11/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

School-based health centers (SBHCs) provide vital behavioral, sexual, and reproductive healthcare services to youth across the United States. Young people who identify as LGBTQ+ are far more likely to deal with adverse health outcomes than their cisgender and heterosexual peers. There are several areas of practice that SBHCs can implement in order to improve services for LGBTQ+ young people and positively impact their wellbeing. These practices include (1) adopting, disseminating, and adhering to LGBTQ+ supportive policies and procedures; (2) creating welcoming physical environments; (3) systematically documenting and using sexual orientation and gender identity information; (4) training all employees in best practices for interacting with LGBTQ+ patients; and (5) developing the clinical workforce to deliver high-quality services to LGBTQ+ patients. The main goal of this study is to test the ability of a implementation model, the Dynamic Adaptation Process, to support SBHCs in putting these practices into place and to examine how these practices impact student satisfaction and engagement with care.

Who can participate?

School-based health centers serving high schools in New Mexico, their staff, and their student patients are eligible to participate in this study. Since the study is focused on improving care and services at an organizational level, individual participants are not required to have a certain health condition.

What does the study involve?

The SBHC personnel will be expected to participate in annual web-based surveys and 1 week of rapid assessment procedure-informed clinical ethnography (RAPICE). The surveys inquire into attitudes about LGBTQ+ people, perceptions of LGBTQ+ supportive guidelines, implementation climate, and work environments. RAPICE will involve direct observations and unstructured interviews.

Once an IRT member is recruited by SBHC personnel, the research team will invite this individual to join the study via email, phone, and/or in-person meetings; their involvement in research activities will entail the completion of evaluation forms related to training activities and participation in a small group interviews, brief surveys, and ethnographic observations performed by the study coach.

Per the DAP, IRT members and other SBHC personnel will collaborate with an implementation coach to complete the LGBTQ+ Practices Checklist to capture data regarding the adoption of specific guidelines. They will use data from this tool to plan for the implementation of the LGBTQ+ supportive guidelines.
High school students who use SBHC services will be asked to complete a self-administered anonymous post-clinic visit survey to assess student perceptions of SBHC settings, barriers to care, satisfaction with care, and engagement.

What are the possible benefits and risks of participating?
There are no individual benefits to participation other than temporary access to free training and technical assistance and the potential satisfaction of contributing to improved services for student patients. The main risk involved in participation is a breach of confidentiality should unauthorized individuals gain access to private information about the participants. Potential risks to participants from such breaches are primarily psychological and social. The researchers will privately collect information regarding the SOGI information from all participants, which could lead to embarrassment if disclosed in public.

Where is the study run from?
Pacific Institute for Research and Evaluation – Southwest Center (USA)

When is the study starting and how long is it expected to run for?
October 2021 to March 2027

Who is funding the study?
National Institute for Nursing Research (USA) (R01NR021019)

Who is the main contact?
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Contact information

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Study information

Scientific Title
Enhancing structural competency in school-based health centers to address LGBTQ+ adolescent health equity

Acronym
SBHCs HELP

Study objectives
School-based health centers will significantly increase the adoption of LGBTQ+ supportive practices.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/05/2022, Pacific Institute for Research and Evaluation (4061 Powder Mill Road, Beltsville, 20705, United States of America; +1 (0)301 755 2757; IRB@pire.org), ref: 1952485

Primary study design
Interventional

Study design
Randomized stepped-wedge trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Enhancing structural competency of school-based health centers

Interventions

Application of the Dynamic Adaptation Process, including coaching, training, and data-driven adaptation of practices and implementation strategies, to support site-specific implementation resource teams to assess, plan, and implement changes to their school-based health centers. Using a randomized stepped-wedge design, each school-based health center serves as its own control comparison as well as a comparator for other centers. All centers eventually receive the intervention.

Sites were randomized into one of three cohorts. Randomization was balanced using the median population served by sites. The intervention will last one year. Follow up will occur periodically for the remainder of the study period, which is determined by when each cohort received the interventions and ranges in duration from 6 to 23 months.

Intervention Type
Behavioural

Primary outcome(s)
Practice adoption is measured using a structured collaborative assessment at baseline and 9-month intervals

Key secondary outcome(s)
1. Organizational readiness to implement evidence-based practices measured by the Organizational Readiness to Change Assessment (ORCA) at baseline and 9-month intervals
2. SBHC staff clinical preparedness and attitudinal awareness measured by the Lesbian, Gay, Bisexual, and Transgender Development of Clinical Skills Scale at baseline and 9-month intervals
3. Implementation climate measured by the Implementation Climate Scale at baseline and 9-month intervals
4. LGBTQ+ community engagement measured by the LGBTQ+ Community Engagement Subscale at baseline and 9-month intervals
5. Acceptability, feasibility, and appropriateness of intervention and implementation strategies measured by the Acceptability, Feasibility, and Appropriateness of Intervention Measure at baseline and 9-month intervals
6. Staff attitudes toward lesbians and gay men measured by the Attitudes Toward Lesbians and Gay Men Scale (ATLG) at baseline and 9-month intervals
7. Staff attitudes toward bisexual people measured by the Bisexualities: Indiana Attitudes Scale-Abridged at baseline and 9-month intervals
8. Attitudes toward transgender individuals measured by the Attitudes Toward Transgender Individuals Scale at baseline and 9-month intervals
9. Willingness to adopt interventions measured by Evidence-Based Practice Attitude Scale at baseline and 9-month intervals
10. Student Perceptions of SBHC settings, barriers to care, satisfaction with care, engagement in care measured by questions adapted from the Youth Engagement with Health Services survey instrument at baseline and 9-month intervals

Completion date
31/03/2027

Eligibility

Key inclusion criteria

Inclusion criteria for SBHCs:
1. Must be part of the state-funded SBHC network
2. Reported willingness to convene an IRT

Inclusion criteria for SBHC personnel:
1. Minimum of half-time employment as a PCP, behavioral health provider, clinic coordinator or other staff (e.g., medical assistant) in an SBHC enrolled in the study
2. Reported ability to complete study measures in English

Inclusion criteria for IRT membership:
1. Minimum of half-time employment as a PCP, behavioral health provider, clinic coordinator or other staff (e.g., medical assistant) in an SBHC enrolled in the study; or identification as a high school professional (e.g., administrator, teacher, staff); or identification as a student or parent /guardian at the high school served by the SBHC
2. Reported ability to participate in meetings and data collection activities conducted in English
3. Reported willingness to engage in DAP-related activities (e.g., assessment, action planning, monitoring)

Inclusion criteria for patients (students):
1. Identification as a high school student served by an enrolled SBHC
2. Ability to complete the patient survey in English or Spanish

Participant type(s)
Patient, Health professional, Employee, Service user, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
13 Years

Sex
All

Key exclusion criteria
Exclusion criteria for SBHCs:
1. Does not serve high school-aged students.

Exclusion criteria for IRT members:
2. Lack of time to participate in periodic surveys and small group interviews (or focus groups)

Exclusion criteria for patients (students):
3. Prior completion of the survey within the current semester

Date of first enrolment
01/04/2023

Date of final enrolment

15/05/2025

Locations

Countries of recruitment
United States of America

Study participating centre
Pacific Institute for Research and Evaluation - Southwest Center
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Sponsor information

Organisation
Pacific Institute For Research and Evaluation

ROR
https://ror.org/01jfr3w16

Funder(s)

Funder type
Government

Funder Name
National Institute of Nursing Research

Alternative Name(s)
National Institute of Nursing Research National Institutes of Health, NINR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

All data will be archived in an NIH repository of the funding institute. The dataset will not be archived until all data collection is completed. The PI will make the data used in publications that do not utilize the final dataset available upon request from an investigator at an institution with a current Federal Wide Assurance (FWA). Each publication will provide a statement on how to access the data.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/11/2024	28/11/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes