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Conducting Intervention Research among Underserved Populations: Lessons Learned and Recommendations for Researchers

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Abstract

Randomized controlled trials (RCTs) are considered the gold standard in research design for establishing treatment efficacy. However, the rigorous and highly controlled conditions of RCTs can be difficult to attain when conducting research among individuals living with a confluence of disability, low socioeconomic status, and being a member of a racial/ethnic minority group, who may be more likely to have unstable life circumstances. Research on effective interventions for these groups is urgently needed, as evidence regarding approaches to reduce health disparities and improve health outcomes is lacking. In this methodological paper we discuss the challenges and lessons learned in implementing the *Lifestyle Redesign® for Pressure Ulcer Prevention in Spinal Cord Injury* (LR-PUPS) study among a highly disadvantaged population. These issues are discussed in terms of strategies to enhance recruitment, retention, and intervention relevance to the target population. Recommendations for researchers seeking to conduct RCTs among socioeconomically disadvantaged, ethnically diverse populations are provided.

Keywords

Spinal Cord Injuries; Pressure Ulcer; Life Style; Vulnerable Populations

The relationship between health, socioeconomic status (SES), and racial/ethnic minority status has been widely documented. Low income, low educational attainment, and minority race or ethnicity have consistently been shown, both independently and in combination, to be associated with poor health and increased risk of health disparities^{1,2}. The relationship between disability and socioeconomic status is bidirectional and follows a gradient, with the

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most disadvantaged experiencing poorer health than the middle class, who are less healthy than society's most privileged^{1,3}. It should not be surprising, then, that these relationships hold true among the approximately 250,000 individuals living with spinal cord injury (SCI) in the United States⁴. Among adults with SCI, lower SES and minority race/ethnicity are associated with decreased life expectancy⁵, higher hospitalization rates^{6,7}, lower employment rates^{7,8}, poorer perceived health⁹, decreased quality of life and life satisfaction⁷, and increased risk of secondary conditions^{10,11}.

Research among low SES and minority adults with disabilities is an urgent priority, as there is limited evidence on efficacious interventions to improve health outcomes in these populations^{1,2,6,12}. However, the constraints of participation in randomized controlled trials (RCTs), the gold standard of establishing intervention efficacy, can be burdensome, particularly for underserved populations who may already be managing complex or chaotic life circumstances. In this paper we present an overview of the challenges encountered by our research team in implementing an RCT among an underserved population, and strategies we have implemented to ameliorate their impact on the study design. The overarching aim of the study, *Lifestyle Redesign® for Pressure Ulcer Prevention in Spinal Cord Injury* (LR-PUPS), is to evaluate the efficacy of a lifestyle intervention in reducing the incidence of medically serious (stage III or IV) pressure ulcers and improving quality of life among adults with SCI.

Participants in LR-PUPS are recruited from a socially and demographically disadvantaged source population. A majority live in medically underserved areas and have low income, low educational attainment, or identify as racial/ethnic minorities at high risk for health disparities. Our research team's previous needs assessment among this population^{13,14} identified that, in addition to these social and demographic factors, many face challenging life circumstances such as criminal backgrounds, gang affiliation, or unstable housing, which create additional barriers to sustaining health behaviors. Under these circumstances, involvement in a clinical trial may represent a significant undertaking. We therefore have sought to be creative and proactive in enabling research participation among a population for whom gold-standard evidence on interventions to improve health and quality of life is limited.

We emphasize that our aim, in describing the challenges of this research, is not to take power or control away from an already-vulnerable population, by casting *participants* as being "challenging" to work with. Rather, the challenge is in meeting the diverse and often complex medical and psychosocial needs of participants, *within the confines of* a methodologically rigorous clinical trial. In essence, the challenge is to reconcile the discrepancy between a highly ordered environment (a randomized controlled trial) and a highly unpredictable environment (the real life circumstances of many participants). As shown in Figure 1, this conflict is primarily mediated by research team members who interface with participants. While all clinical research faces this challenge to a certain degree, the population and community-based context of this study particularly foregrounds these issues. Our goal is to encourage other researchers to conduct similar work among underserved populations, through providing practical suggestions gleaned from our experiences.

Spinal Cord Injury and Pressure Ulcers

Pressure ulcers are a common medical complication of SCI, with an incidence of approximately 15.2% in the first year after injury¹⁵. Their incidence increases over time and with more severe injuries, ranging from 5.6% in individuals with incomplete paraplegia in the first year post-injury, to 40.6% in individuals with complete tetraplegia 20 years post-

injury¹⁵. Two recent studies of individuals with SCI found that skin disorders, including pressure ulcers, were second only to urinary tract infections as a reason for rehospitalization^{16,17}. Chronic pressure ulcers are associated with a 4.52 greater odds of mortality (CI 2.57–7.94) among adults with spinal cord injury¹⁸. Developing an initial pressure ulcer is the strongest predictor of experiencing recurrent pressure ulcers¹⁹; additional predictors include low household income, African-American race, comorbid conditions, low educational attainment, unemployment, lack of physical activity, smoking, depression, equipment failures, and longer sitting time^{10, 20–24}.

In addition to negatively impacting health and quality of life, pressure ulcers exact a significant financial cost. A multisite study of 10,977 veterans with SCI found that those who developed a pressure ulcer averaged 52 more annual inpatient hospitalization days, and significantly higher total annual healthcare costs (\$100,935 vs. \$27,914; $p < 0.001$), than those without pressure ulcers⁴. Inpatient hospital costs for treatment of a stage IV ulcer and associated complications average \$127,185 per hospitalization²⁵. Major cost drivers for pressure ulcer management include caregiving costs, pressure-reducing surfaces, medications and dressings, physician visits, surgical debridement and repair, hospital admissions, and management of comorbid conditions such as infections²⁶.

Challenges of Conducting Research among Disadvantaged Populations

The need to include ethnically and socioeconomically diverse populations in clinical research is widely acknowledged^{27,28}; however, significant challenges have been identified in recruiting, retaining, and implementing culturally relevant interventions in diverse populations. First, the extent to which language barriers can interfere with research is often underestimated. Translators not fully versed in a project's purpose or methodology may unintentionally misrepresent the study when interacting with participants, introducing potential bias²⁹. Additionally, qualitative and quantitative measures are subject to systematic error when attention is not paid to both the cultural relevance of the constructs being measured and the translation process^{30,31}.

Second, the intersection between low SES and racial/ethnic minority status is frequently not addressed. For instance, the Hispanic/Latino population in the United States is extremely diverse, encompassing monolingual English speakers born in the U.S., long-term immigrants who are fully bilingual and highly acculturated, recent immigrants who may or may not speak English, and undocumented immigrants who often do not speak English. Distinct subgroups such as these often present divergent health and lifestyle issues, and disentangling the relative contributions of SES and race/ethnicity to health disparities presents a major methodological challenge³¹.

Finally, professionals with higher levels of education and socioeconomic circumstances may not be familiar with the lifestyles, actions, and motivations of individuals from disadvantaged populations, leading to mismatched expectations. For example, clients who recurrently miss appointments may be labeled as non-compliant or having poor follow-up, whereas clients may not have the financial or logistical means to attend the appointment or may feel that the intervention is irrelevant or unhelpful in addressing their needs³². Such misunderstandings can result from professionals' limited awareness of the impact of poverty, disability, and minority status on everyday life³². The cumulative stress of inadequate financial resources, unmet social service needs, a degraded physical environment, and the sense of helplessness and hopelessness that may develop in such circumstances can contribute to a lifestyle which has been identified as life chaos. Life chaos is conceptualized as a lack of structure and organization in everyday life, inability to develop and sustain habits and routines, and difficulty planning for the future³³. A high degree of life

chaos has been shown to influence a range of health and psychosocial outcomes. For example, among adults with HIV, increased life chaos is associated with decreased ability to access appropriate health services and lower mental health status³³. Among low-SES families, life chaos mediates the impact of poverty on adolescents' socioemotional development³⁴. Finally, among adults with SCI, chaotic lifestyles have been identified as a risk factor for developing pressure ulcers¹³.

Aims and Research Design of the LR-PUPS Study

The LR-PUPS Study is a community-based RCT evaluating the efficacy and cost-effectiveness of a lifestyle intervention aimed at preventing medically serious [stage III or IV] pressure ulcers and improving quality of life among adults with SCI. 170 participants were stratified into one of three groups according to pressure ulcer risk: (1) low risk (zero or one medically serious pressure ulcers within the past two years); (2) high risk (two or more medically serious pressure ulcers within the past two years); or (3) a current stage III pressure ulcer. Within each stratum, participants were randomized to either the LR-PUPS intervention (n=83) or a control group (n=87) which receives no study-related intervention, but has ongoing access to usual care.

The theoretical framework guiding the LR-PUPS intervention was developed from the findings of the Pressure Ulcer Prevention Project (PUPP) needs assessment, recruited from the same source population as the LR-PUPS study³⁵. The PUPP study yielded targeted information about personal and contextual factors influencing pressure ulcer risk in community-dwelling adults with SCI. Data from PUPP were used to generate models delineating the processes through which pressure ulcers develop¹⁴ and identify key principles contributing to pressure ulcer development in everyday life contexts¹³. These findings, as well as principles of Lifestyle Redesign[®]^{36, 37} (as specified in the intervention manual for the USC Well Elderly Studies^{36, 38} on which the last author served as Principal Investigator), motivational interviewing,³⁹ and extant knowledge on lifestyle factors contributing to pressure ulcer risk^{10,21,23,24}, were used to construct the LR-PUPS treatment manual⁴⁰.

The LR-PUPS intervention is delivered by a team of licensed occupational therapists, with a registered nurse providing wound care consultation. The first 6 months of the intervention, termed the 'intensive phase,' consists of weekly sessions, delivered face-to-face in participants' homes and communities or by telephone. This is followed by a 6-month 'tapered phase,' comprised of biweekly telephone sessions and two in-person visits. Additionally, incident-based contacts are initiated as needed to address emergent episodes of pressure ulcer risk or skin breakdown. Finally, intervention recipients may obtain up to \$400 in supplies or equipment relevant to pressure ulcer prevention.

The primary outcomes to test the efficacy of the intervention include: (1) the number of medically serious pressure ulcers and ulcer-related surgeries; (2) ulcer-related medical expenses; and (3) quality of life. These outcomes are assessed through questionnaires and skin check using the Bates-Jensen Wound Assessment Tool (BWAT)^{41,42} at enrollment, 12 months, and 24 months, and a review of medical and billing records at 12 and 24 months. Lastly, on a quarterly basis, participants complete telephone interviews regarding their healthcare utilization and health status. The study was conducted in accordance with the ethical standards of the Los Amigos Research and Education Institute and University of Southern California Institutional Review Boards.

LR-PUPS Participant Characteristics and Strategies for RCT Implementation

Demographic and Psychosocial Characteristics of LR-PUPS Participants

Table 1 provides baseline demographic data for LR-PUPS participants (n=170). Approximately 54% of participants have monthly household incomes under \$1000 (75% under \$2000) and 36.5% lack a high school diploma or equivalent. The majority of participants identify their racial or ethnic background as Hispanic/Latino (49%) or Black/African-American (32%). In addition, to better characterize the life circumstances of LR-PUPS study participants, we conducted a secondary analysis of psychosocial risk factors affecting participants, presented in Table 2. This assessment was conducted among the intervention group only; given the randomized study design, we anticipate that the incidence of risk factors is similar in the control group. Data were compiled through a review of participants' medical records, LR-PUPS treatment notes, and clinical assessments made by the LR-PUPS interveners based on their sustained engagement with participants and family members, in their homes, over a 12-month period. The seven risk factors were selected on the basis of feedback from the LR-PUPS intervention team regarding psychosocial issues which interfered with participants' ability to implement pressure ulcer prevention strategies in their everyday lives.

Data in Table 2 are presented for the intervention group as a whole (n=83), and separately for participants who are neither low-income nor underrepresented minorities (n=9), who are either low-income or underrepresented minorities (n=18), and who are both low-income and underrepresented minorities (n=56). These categories were established on the basis of extant literature^{1,2} that low SES and racial/ethnic minority status contribute to health disparities both independently and in combination. This finding is borne out in the current study, as across these categories, there was a marked difference in the distribution of risk factors. In the high-income, non-minority group, 67% had no risk factors, and none had 3 risk factors. Among those who were either low-income or underrepresented minorities, 33% had zero risk factors, while 28% had 3 risk factors. Among those who were both low-income and underrepresented minorities, 18% had no risk factors, while 45% had 3 risk factors.

Strategies for Community-Based RCT Implementation in Diverse Populations

As illustrated in Figure 1, we conceptualize the challenge of conducting an RCT among a disadvantaged population as stemming from the discrepancy between the ideal implementation of an RCT under highly controlled, stable conditions, and the often unpredictable life circumstances of many study participants. This mismatch requires particular care to resolve, to ensure a positive experience for research participants while maintaining the methodological rigor required of an RCT. Because our research team had a history of sustained engagement with the source population^{13,14}, as well as previous experience conducting community-based RCTs among ethnically and socioeconomically diverse populations^{36,38}, we embedded, *a priori*, several strategies to facilitate successful recruitment, retention, and intervention in the present study.

The study team utilized a consumer advisory board in the formative stage of the present study to consult on issues related to recruitment, retention, and intervention strategies. We also included a consumer representative on the study's Data and Safety Monitoring Board, which provides ongoing oversight on issues related to the recruitment and retention of underrepresented groups, and safety of research participants. Finally, consumer input gleaned during the in-depth needs assessment^{13,14} was essential in developing an intervention model responsive to the needs and concerns of the target population.

We also assembled a project team that reflects, to a high degree, the diverse backgrounds of participants. Intervention recipients are matched with occupational therapists on the basis of language concordance, racial/ethnic background, and, when possible, gender. All staff members who have contact with Spanish-speaking participants are fully bilingual. Finally, staff members whose backgrounds are dissimilar from participants' receive extensive mentoring on cultural norms and appropriate behavior in situations they may be unaccustomed to encountering, such as conducting assessment sessions in impoverished or high-crime neighborhoods.

Recruitment was identified as a potential challenge at the study's outset, leading the study team to pursue several strategies to ensure attainment of the 170-participant sample within the planned timeframe. Recruitment was overseen by a bilingual Latino faculty member trained by recruiters from a previous RCT which had attained an ethnically and socioeconomically diverse sample³⁸. A diverse recruitment team was assembled with the goal of enhancing cultural sensitivity and reducing distrust and perceptions of discrimination on the part of prospective participants. Of the five recruiters, two were Hispanic/Latino, one was African-American, three were fluent Spanish speakers, and one had a spinal cord injury. The recruiters also utilized cultural brokers at the study's clinical site, establishing relationships with physicians, nurses, therapists, and other staff. Endorsements and referrals from these respected clinicians and staff members helped to enhance the perceived value of the study and decrease distrust of the recruitment team.

Methodological Challenges and Lessons Learned

While the strategies identified above are helpful in facilitating successful study implementation, the research team has identified 6 themes that illustrate unanticipated, additional challenges nevertheless encountered when conducting an RCT among an underserved population. Themes were derived through an iterative process which began with observations of recurring challenges noted at weekly research team and intervention team meetings. These themes were then discussed and refined by the study authors until consensus was achieved. The themes identified through this process include: (1) tracking and scheduling participants; (2) retaining staff; (3) collecting accurate data; (4) negotiating health and socioeconomic tradeoffs; (5) understanding life and medical histories; and (6) defining the scope of the intervention. The first three themes illustrate overarching challenges of RCT implementation, while the latter three primarily relate to intervention delivery.

Tracking and Scheduling Participants

While tracking participants is a major undertaking in any clinical study, a study population with a high degree of life instability generates particular challenges. Common impediments to maintaining contact with participants include relocation or loss of housing, financial difficulties leading to phone disconnection, incarceration, irregular work schedules, and emergent medical issues requiring hospitalization. To date, 30% of randomized participants have been unreachable for a period of three months or more due to one of the above issues, only to later resume study participation. Despite the challenge of maintaining consistent contact with participants, we have been able to contact and collect outcome data from 94.6% of randomized participants (excluding those who died or formally withdrew from the study) who have thus far completed the 24-month study period.

We have developed several strategies to maintain contact with participants who are highly transient and have limited means of communication. First, we are proactive in maintaining current contact information for participants as well as several additional persons with whom they have regular contact. When participants and their alternate contacts are not reachable,

staff members visit their last known address to attempt to establish contact. We also collaborate closely with staff at our clinical site, who notify the research team if any participants lost to follow-up contact their office.

Another key strategy for maximizing retention and maintaining consistent and ongoing communication with participants has been having a stable point of contact for study participants. The LR-PUPS project assistant position has been filled by the same person for the duration of the study; she contacts participants numerous times to schedule testing, pay stipends, and arrange for equipment deliveries, and answers the main phone line for the study office. Since she is frequently and consistently in contact with study participants, the project assistant can identify those at high risk for loss to follow up and is particularly vigilant about maintaining contact with these individuals.

Caregiver availability to assist with study activities is also a barrier. For example, a participant with tetraplegia who lived in a nursing home was unable to complete phone interviews because he could not rely on the staff to provide a private place to talk, and the equipment he needed to use the phone independently. In this instance, the study design was modified and instead of conducting phone interviews, testers visited the participant to complete interviews in person. For this and other changes to the study protocol, IRB approval was obtained and the study's Data and Safety Monitoring Board was consulted regarding the impact of the proposed protocol changes on the integrity of the research design.

Retaining Staff

Given many participants' unpredictable schedules, carrying out testing and intervention sessions is an ongoing challenge. The difficulty in keeping appointments has created challenges in staff retention, particularly for staff who are employed part-time on the study but also work elsewhere, as they, in turn, have difficulty maintaining predictable schedules. For example, over 3.5 years, the study has employed 17 data collectors and 11 nurses. Other contributors to staff turnover include neighborhood safety concerns and the study's large catchment area (100 miles from our primary clinical site), which leads to frustration with lengthy commute times, particularly when participants are not available for scheduled appointments.

We have addressed these issues by compensating staff for travel time even in the case of missed appointments, and by confirming appointments multiple times through multiple channels. We have also found that employing students as data collectors lessens this problem, as they have more flexible schedules and less dependence on a steady income. For intervention staff, we offer part-time positions on LR-PUPS and, when feasible, complement this with more stable work to guard against burnout. Utilizing these strategies, while effective, has required a significant investment of time and financial resources.

Collecting Accurate Data

Outcome data for this project are captured through several mechanisms, including telephone interviews, in-person questionnaires and skin checks, and review of medical and billing records. Some of the difficulty in data collection has been related to the considerable challenge of scheduling and keeping appointments, as previously discussed.

Capturing data from participants' medical records has also been less straightforward than anticipated, for several reasons. First, our primary clinical site is a large county hospital, and shares the challenges facing overburdened public healthcare facilities throughout the United States. This situation has contributed to delays in obtaining participants' medical records, requiring additional research team staffing to compensate. The facility's limited resources

also contribute to long wait times for appointments, which in turn lead some participants to seek care elsewhere, either voluntarily, or out of necessity because their condition worsens before their appointment date. Finally, when participants do have medical visits, their charts sometimes contain data which are difficult to interpret, preventing the research team from drawing firm conclusions regarding the severity of pressure ulcers. For example, some ulcers are described by their size or appearance but not staged. Others are noted as being “stage II–III,” creating ambiguity as to whether they qualify as non-serious (stage I or II) or medically serious (stage III or IV) ulcers.

To enhance the accuracy of our data collection given these concerns, we modified our approach to measuring our outcome variables as the study progressed. One significant change was the implementation of in-home pressure ulcer assessment for all study participants at baseline, 12, and 24 months. Previously, the assessment was administered by personnel at an outpatient pressure ulcer management clinic during participants’ regularly-scheduled visits, which was problematic for the reasons described above. This change has required a significant investment of resources in the form of additional personnel, stipend payments to participants for skin checks, and staff time to re-consent participants according to the new protocol, perform skin checks, and evaluate pressure ulcer data.

Negotiating Health and Socioeconomic Tradeoffs

Many LR-PUPS participants are disadvantaged in multiple respects and have little control over aspects of their lives relevant to maintaining health, such as neighborhood safety, transportation, and material living conditions (e.g. accessible bathing and toileting, sleeping surfaces adequate to maintain skin integrity). To meet their basic needs, many rely on overstrained public services, and caregivers who are struggling to balance multiple competing priorities. Crisis situations, such as becoming homeless, acute illness, being arrested, or the death of a loved one are not infrequent occurrences for some participants. Such conditions are a source of chronic stress, and can create significant obstacles in attending to health needs, including pressure ulcer prevention.

Many participants live in complex, interdependent family systems that ensure the stability and subsistence of the family collectively, but leave limited resources available to minimize an individual’s pressure ulcer risk. For instance, it is common for a family member to assume the role of caregiver, a service for which he or she is paid by the state. In some cases, these family members face constraints on their caregiving abilities due to physical limitations, incomplete understanding of the participant’s medical needs, or competing demands on their time such as paid work or caring for other family members. However, because the family as a whole depends on the income generated from caregiving, the participant is unable to hire another caregiver from outside the family. In such situations, interveners must think creatively to enable the participant, caregiver, and other family members to implement pressure ulcer prevention strategies that are sustainable given these care challenges.

In other cases, pressure ulcer prevention strategies may be impractical to implement due to participants’ socioeconomic circumstances. Living in poverty compels some participants to find creative ways to earn income or minimize expenses, some of which may heighten pressure ulcer risk. One approach to earning income used by several participants is selling goods on the street. As this necessitates that they be in their wheelchairs for extended periods, they are unable to minimize sitting time, a common recommendation for reducing the risk of pressure ulcers. For individuals with pressure ulcers, increasing dietary protein is often suggested to facilitate wound healing. However, many participants have limited access to high-quality protein sources such as lean meats or low-fat dairy due to cost, availability, cultural preferences, or feasibility of preparing these foods. At times, because the

intervention is implemented in participants' homes, LR-PUPS interveners witness substandard living conditions that were kept hidden from professionals in other settings. For instance, one participant bathed in his backyard with a garden hose, because the bathroom in his home was inaccessible. Another, on bedrest to heal a pressure ulcer, had unsanitary bed linens, increasing his risk for infection. Such issues have required the intervention team to develop an extensive knowledge of community resources and draw upon multiple social services to address the pervasive consequences of poverty that exacerbate pressure ulcer risk.

Understanding Life and Medical Histories

LR-PUPS participants may sometimes, either unintentionally or strategically, relay information to professionals in ways that lead to misunderstandings. Poorly understood life and medical histories result from participants withholding or providing contradictory information about pressure ulcers and life circumstances. In some cases this is because they view the information as trivial or unimportant. In others, it is a strategy utilized to elicit social support or other resources. For example, a participant may not share information perceived to be socially unacceptable in order to gain the intervener's approval, or conversely, overemphasize unpleasant living conditions to elicit sympathy. Participants involved in illegal activities rarely share this information with interveners, particularly early in the therapeutic relationship, although these activities sometimes substantially increase pressure ulcer risk. When participants eventually do disclose their involvement in such activities, interveners have assisted them in implementing prevention strategies within these contexts. For example, when an intervener discovered that a participant kept illegal drugs rolled into a bundle in his sock, she was able to involve him in a discussion regarding how his drug use could increase pressure ulcer risk.

Owing to the unique life circumstances of some participants, some of which may be derided in the mainstream culture, interveners' primary focus is to establish and sustain a positive therapeutic relationship with participants. We have found that it is particularly important for interveners to proactively assert their non-judgment of participants' lifestyles in order to develop sufficient trust and rapport to influence aspects of their lives that heighten pressure ulcer risk. Incorporating motivational interviewing principles into the intervention has been an effective strategy in this regard, as it elicits participants' own arguments in favor of behavior change (in contrast to a prescriptive approach)³⁹. This allows interveners to remain empathetic toward participants while encouraging progress toward lifestyle changes that may reduce pressure ulcer risk.

Defining the Scope of the Intervention: Avoiding Blurring Roles

The LR-PUPS team manages a unique constellation of circumstances in implementing a manualized, yet highly individualized, intervention, in community settings, among a population with multiple barriers to preventing pressure ulcers. Intervenors treat clients in their homes and neighborhoods, often outside of usual business hours, and may develop intervention goals in domains very different from more traditional biomedical approaches to pressure ulcer prevention. In this context, it is difficult, but imperative, to clearly define the scope of the intervention and the relational boundaries between participant and intervener. Therefore, the intervention team has maintained a high degree of vigilance around the danger of blurring roles.

Blurring roles occur when interveners believe that a participant, implicitly or explicitly, is requesting assistance that goes beyond the scope of the intervention and their role as a professional focused on pressure ulcer prevention. The nature of the LR-PUPS intervention often blurs participants' perceptions of the intervener, who they come to see as a resource

for solving problems that may not directly relate to pressure ulcer risk. The relationship between a participant's life situation and pressure ulcer risk can be ambiguous, making it difficult to determine whether to intervene. For example, participants have asked interveners to mediate in family disputes or provide financial support for activities that are only peripherally relevant to pressure ulcer risk.

One strategy we have used to resolve this issue is for the intervener to address only the aspect of the situation that relates to pressure ulcer risk. For example, when a participant requested help from an intervener to move to a new home, the intervener did not provide material assistance during the move, but discussed strategies for implementing pressure reliefs during the process of moving, and for pressure ulcer prevention in the context of his new living situation. Another effective strategy has been for the intervener to consult with the research team regarding a potentially problematic request. This allows the intervener to diffuse tension by attributing responsibility for the denial of a participant's request to a third party not involved in the therapeutic relationship. Such concerns typically are discussed at weekly intervention team meetings, which have become an important venue for problem-solving potential boundary issues.

Conclusions and Recommendations for Researchers

Poverty and disability, and their impact on life stability, are significant factors to consider when planning clinical research among populations living under these conditions. While the LR-PUPS research team had prior experience working with this population^{13,14}, the scope of a large-scale community-based RCT, and the rigor required for its successful implementation, expanded the magnitude of both the challenges faced by the research team and the resources needed to resolve them.

Carrying out the research protocol with fidelity, and in the specified timeframe, has required significantly more resources than similar studies conducted by our research team among populations with equivalent socioeconomic circumstances, but somewhat greater life stability^{36,38}. In this regard, researchers aiming to implement studies among underserved populations should be realistic in assessing the impact of participants' life circumstances on their estimates of the time, financial resources, and personnel needed to carry out particular research tasks. A consumer advisory board with membership drawn from the source population may provide valuable insight regarding effective and efficient strategies for recruitment, retention, and intervention delivery, particularly for researchers who do not have a background of sustained engagement with the population they hope to serve. Given the resources needed to maintain the methodological rigor of the present RCT, upon completion of the trial, an analysis of the most cost-effective strategies for promoting fidelity to the study protocol may provide important data for future research with underserved populations.

The challenges we have described can easily induce frustration. Therefore, flexibility, persistence, patience, and creativity are particularly important attributes to consider in assembling a research team and hiring professional and administrative staff to implement the study protocol. Ensuring that staff members have adequate resources and support, and recognizing successes and milestones in the course of the project, can help boost morale, alleviate burnout and maximize staff retention.

Finally, approaching intervention delivery from the perspective of participants' worldview and life experience is of utmost importance. Although participants may at times seem disinterested in the intervention, what appears to be a lack of interest can indicate life chaos, or hopelessness that the intervention will improve their life circumstances. To address this, interveners must devote significant effort to understanding the complexity of participants'

life circumstances, developing rapport, and proactively expressing non-judgment about life choices which may endanger the participant's well-being, but which the participant is unwilling or unable to change. When interveners, whether purposefully or unconsciously, impose their values and worldview on clients, the likely result is misunderstandings that undermine the therapeutic relationship and lessen the impact of the intervention.

In conclusion, research investigating effective rehabilitation interventions among underserved populations is sorely needed. However, because of the significant investment required to carry out these trials successfully, researchers should be cognizant beforehand of potential pitfalls unique to this research. Although the unique challenges associated with community-based rehabilitation intervention studies may seem formidable, they are also capable of being effectively handled. In this paper, we have provided an overview of practical solutions that can be adopted in future research aiming to lessen the significant health disparities among underserved populations. Our objective in sharing the lessons we have learned from the LR-PUPS study is to assist other researchers in carrying out this important work.

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Abbreviations

BWAT	Bates-Jensen Wound Assessment Tool
HIV	Human immunodeficiency virus
LR-PUPS	Lifestyle Redesign® for Pressure Ulcer Prevention in Spinal Cord Injury
PUPP	Pressure Ulcer Prevention Project
RCT	Randomized controlled trial
SCI	Spinal cord injury
SES	Socioeconomic status

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Figure 1.
Mediation Model of RCT Context and Participants' Life Context

Table 1

Social and Demographic Characteristics of LR-PUPS Participants (n=170)

	N(%) or Mean(SD)
Sex	
• Male	144 (84.7%)
• Female	26 (15.3%)
Age (years)	42.2 (12.5)
Education	
• # of years	12.1 (3.4)
• < High school degree or GED	62 (36.5%)
Household income	
• \$0–\$999/mo.	92 (54.1%)
• \$1000–\$1999/mo.	35 (20.6%)
• \$2000/mo.	39 (22.9%)
• Not stated	4 (2.4%)
Race/Ethnicity	
• Hispanic/Latino	83 (48.8%)
• Black/African-American	54 (31.8%)
• White	22 (12.9%)
• Other	11 (6.5%)
Residence	
• House/apartment/condo	160 (94.1%)
• Assisted living/nursing home	7 (4.1%)
• Other	3 (1.8%)
• Years at current residence	9.7 (10.3)
Level of Injury	
• Paraplegia	124 (72.9%)
• Tetraplegia	45 (26.5%)
• Unknown	1 (0.6%)
Presence of Caregiver	
• Yes	140 (82.4%)
• No	30 (17.6%)
• Median (interquartile range) hours per week of paid and unpaid care	35.5 (7.0, 71.0)
Pressure Ulcer Risk	
• Low*	100 (58.8%)
• High**	67 (39.4%)
• Current Stage III pressure ulcer	3 (1.8%)

* < 2 serious pressure ulcers (stage III or IV) in the past two years

** 2 serious pressure ulcers in the past two years

Table 2
Incidence of Psychosocial Risk Factors among LR-PUPS Intervention Recipients

Psychosocial Risk Factor	All intervention participants (n=83)	High income [†] /non-minority [‡] participants (n=9)	Low income [†] OR underrepresented minority [‡] participants (n=18)	Low income [†] AND underrepresented minority [‡] participants (n=56)
• High pressure ulcer risk	36 (43.4%)	3 (33.3%)	6 (33.3%)	27 (48.2%)
• Drug/alcohol abuse or dependence	27 (32.5%)	3 (33.3%)	5 (27.8%)	19 (33.9%)
• Gang affiliation	13 (15.7%)	0 (0.0%)	3 (16.7%)	10 (17.9%)
• Unstable housing or homelessness	14 (16.9%)	0 (0.0%)	2 (11.1%)	12 (21.4%)
• Involved in illegal activity (excluding drug possession for personal use)	26 (31.3%)	0 (0.0%)	5 (27.8%)	21 (37.5%)
• Incarceration or involvement in criminal justice system	16 (19.3%)	0 (0.0%)	4 (22.2%)	12 (21.4%)
• Not eligible for health and social service programs *	15 (18.1%)	0 (0.0%)	2 (11.1%)	13 (23.2%)
• Etiology of injury due to interpersonal violence (e.g. gunshot wound)	44 (53.0%)	1 (11.1%)	8 (44.4%)	35 (62.5%)

[†] High income defined as household income \$2000 per month or not stated; low income defined as household income <\$2000 per month.

[‡] Underrepresented minorities include all participants who either report their ethnicity as Hispanic or Latino or their race as Black/African American. Non-underrepresented minorities include those who report their ethnicity as Not Hispanic or Latino and report their race as White, Asian, American Indian or Alaska Native, or Native Hawaiian or Other Pacific Islander.

* We do not inquire about participants' immigration status, but failure to qualify for MediCal (California's Medicaid program), Medicare, or social service programs such as food stamps, when one otherwise meets eligibility criteria, may indicate undocumented status.

• **High pressure ulcer risk:** Two or more medically serious (stage III or IV) pressure ulcers within the past two years, or a current stage III pressure ulcer.

• **Drug/alcohol abuse/dependence:** Current or former abuse or dependence on alcohol, illegal drugs, or inappropriate use of prescription drugs. Excludes recreational drug use with no evidence of addiction.

• **Gang affiliation:** Past or current involvement in gang activity; whether confirmed by participant or by caregiver/family member.

• **Unstable housing/homelessness:** Not having permanent housing; "couch surfing" or staying with friends; having "permanent" residence but spending most nights elsewhere because of problems at home.

• **Illegal activity:** Past or current involvement in illegal activities such as selling drugs, assault, weapons charges, robbery, etc. Excludes drug possession for personal use (without intention to sell).

• **Incarceration/criminal justice involvement:** History of being in jail, prison, or juvenile facility, and/or having been on probation.

• **Ineligible for health/social services:** Person does not qualify for medical benefits and social services normally extended to legal U.S. residents meeting eligibility criteria.

• **Violent etiology of SCI:** SCI caused by violence, such as gunshot wound, stab wound, or result of altercation (e.g. car accident while being chased by someone). Excludes general high-risk behavior (e.g. car accident due to drunk driving) in absence of interpersonal violence.