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Self-efficacy and social support enable women to protect their pelvic floor health: A nonrandomized controlled trial in rural Nepal

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Abstract

Carrying heavy loads increases the risk of pelvic organ disorders, particularly in low-income countries. Low self-efficacy hampers adoption of pelvic-floor-protective behaviors. The enabling hypothesis suggests that social support may strengthen women's behavioral self-efficacy. A three-arm parallel non-randomized controlled trial with 300 women and their social partners experimentally examined whether self-efficacy and social support can enable women's pelvic-floor-protective behaviors in rural Nepal. Three villages received (1) self-efficacy (2) self-efficacy and social support promotion, or (3) information only control. The co-primary outcomes were reduced weight carried and using protective lifting techniques at 2-month follow-up. Self-efficacy promotion increased the use of protective lifting techniques 9% more than information only (d = 0.28). Weight was reduced by 3 kg more when additionally promoting social support compared to self-efficacy alone (d = 0.39). Self-efficacy and social support promotion enable women to better protect their pelvic floor health and may complement educational approaches to health behavior change in low-resource populations.

Keywords

health behavior change intervention, low resource populations, self-efficacy, social support, Women's health

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Pelvic Floor Muscle (PFM) disorders affect one in three women worldwide and include urinary incontinence, bowel dysfunction, and pelvic organ prolapse (pelvic organs' descent into or out of the vagina; Jelovsek et al., 2007). Carrying heavy loads is one of the main modifiable risk factors for pelvic organ disorders (Biswokarma, 2016; Shaw et al., 2014), particularly in low- and middle-income countries. Households often rely on water sources off premises and wood as primary energy source, which entails women to carry heavy loads such as 20 kg water containers and firewood, also in Nepal (Earth and Sthapit, 2002; Geere et al., 2010; Meierhofer et al., 2022; Tomberge et al., 2021, 2022).

Adopting pelvic-floor-protective carrying behaviors can reduce intra-abdominal pressure and support PFM when carrying loads and are thus promising to reduce the risk of damaging the pelvic floor: First, carrying less weight can reduce intra-abdominal pressure and pelvic organ disorders (MacDonald et al., 2013; O'Dell, 2006; Shaw et al., 2014), and thus represents one promising approach to pelvic-floor-protective carrying. A second protective carrying behavior is to apply pelvic-floor-protective lifting techniques: Co-contracting the PFM before and during lifting helps to cope with high intra-abdominal pressure such as lifting in terms of stabilizing the PFM (Biswokarma, 2016; Bø, 2006). Researchers found that exhaling during lifting, also implemented in physiotherapy settings in combination with PFM co-contraction (Prather et al., 2009), reduces intraabdominal pressure. (Hagins et al., 2004; Niederauer et al., 2023).

Previous studies have shown that women are interested and able to learn health behaviors to prevent pelvic floor disorders as part of an intervention (Biswokarma, 2016; Caagbay et al., 2020; Tomberge et al., 2022). In Nepal, for example, Caagbay et al. (2017, 2020) developed an educational intervention promoting life style advice, including protective carrying behavior, which was successful in promoting quality of life and PFM awareness. However, informational interventions alone might not be effective in enabling women's health behavior in low-resource populations because limited social or financial resources can limit their behavioral self-efficacy (Greene and Murdock, 2013; Schüz et al., 2020; Tomberge et al., 2022, 2024). According to Greene and Murdock (2013) "individuals living at lower levels of the socioeconomic status hierarchy [more likely believe that] they [have] less competence to exert control over their lives through achieving goals [. . .]" (p. 234).

Self-efficacy signifies an individual's self-confidence in their capacity to prepare, initiate, and maintain behavior, even if obstacles emerge (Bandura, 1977). Bandura specifies four major sources of self-efficacy: performance accomplishments, in which individuals experience that they can successfully perform protective carrying; vicarious experience, which involves awareness that meaningful others successfully practice protective carrying; verbal persuasion, which is delivered through positive feedback and encouraging messages; and emotional arousal, which entails feeling relaxed rather than aversively aroused when practicing protective carrying (Bandura, 1977).

Additionally to these sources, Benight and Bandura (2004) outlined an enabling effect of social support in which a supporting person equips the recipient with the personal resources to cultivate their ability and self-efficacy to initiate health behavior and maintain it when difficulties arise (Benight and Bandura, 2004; Chehreh et al., 2021; Schwarzer and Knoll, 2007). This is called the enabling hypothesis. The enabling hypothesis emphasized the importance of promoting self-efficacy and social support to change behavior in challenging contexts (Benight and Bandura, 2004). Precisely, Benight and Bandura (2004) described that social support is particularly helpful to promote behavioral self-efficacy in persons who experience a feeling of limited control in life, that is, persons in challenging contexts. Social support

can be defined as resources provided by others, coping assistance, or an exchange of resources (Schwarzer and Knoll, 2007). Social support can be emotional (e.g. encouraging women to practice protective carrying and making them feel valued when they do), informational (e.g. giving advice on how to practice protective carrying), and instrumental (practical assistance, e.g. taking over parts of the carrying tasks; Schwarzer and Knoll, 2007; Tomberge et al., 2022).

Intervention studies to promote self-efficacy and social support can use behavior change techniques, defined as replicable components designed to change behavior, such as verbal persuasion or comprising joint Dyadic Behavior Change Techniques (DBCTs) such as cooperative learning of the behavior and cross-over DBCTs such as a social partner providing social support (Michie et al., 2013; Scholz et al., 2020). Intervention studies have used behavior change techniques to promote self-efficacy or social support and successfully enhanced multiple health behaviors such as exclusive breastfeeding, use of cleaner cooking solutions and physical activity (Chipojola et al., 2020; Goodwin et al., 2015; Luszczynska et al., 2016). Although previous research have found that self-efficacy and social support are main enablers of pelvic-floor-protective behaviors or protective carrying behaviors (Raman et al., 2014; Tomberge et al., 2022, 2024), no such studies have promoted such behaviors in low-resource settings.

Aims of the present study and hypotheses

Guided by the enabling hypothesis, we aim to test for the first time whether the promotion of self-efficacy and social support can enable women's pelvic-floor-protective behaviors in a low-resource setting. We aim to increase pelvic-floor-protective carrying behaviors to reduce the health risks of carrying heavy loads in rural Nepal (i.e. reducing weight carried and applying pelvic-floor-protective lifting techniques). This is the first study involving carrying behaviors from the perspective of health behavior theory. First, to test whether a psychological intervention that promotes self-efficacy can promote women's use of protective carrying behaviors, we hypothesized that women who received self-efficacy interventions either alone or with social support exhibit increased use of protective lifting (H1a) and greater reduction in weight carried (H1b) compared to an information-only control condition. Based on the enabling hypothesis, we further investigated whether including a social partner in the intervention is more effective than individual psychological intervention. We therefore hypothesized that women who received self-efficacy and social support indicate increased use of protective lifting (H2a) and greater reduction of weight carried (H2b) than women who received the self-efficacy-only intervention condition. To investigate the mechanism of the interventions we tested the hypotheses that increased self-efficacy (H3) or increased received social support (H4) explain the intervention effects on the use of protective carrying behaviors. Finally, we explored whether the reduction of weight carried relates to increased carrying frequency as a coping mechanism and whether the participation in the study improves women's psychosocial well-being and symptoms of pelvic organ prolapse over time.

Methods

A nonrandomized controlled trial with a three-arm parallel group design was devised and preregistered https://clinicaltrials.gov/ct2/show/record/NCT05154006 and conducted from January to April 2022 in three rural villages in the Kavre and Sindhupalanchowk districts of Nepal. This is a typical low-income region with health centers affiliated to Dhulikhel Hospital, where the second author is based. The three intervention conditions provided self-efficacy, self-efficacy and social support, and

information only (control). The village-based allocation of interventions prevented the transfer of information within villages (Benjamin-Chung et al., 2018). The study was approved by the Ethical Boards of Ethical Review Committee of the Nepal Health Research Council [514/2021] and the Ethical Board of the University of Bern, Switzerland [2021-10-00005]. We used "Guidelines for Reporting Non-Randomized Studies" to report the methods of this study (Reeves and Gaus, 2004).

Population and sample

Three out of five villages from a previous study on water carrying (Meierhofer et al., 2022; Tomberge et al., 2021, 2022, 2024) were purposely selected to ensure their similarity in carrying behavior (kg per trip, carrying during pregnancy/postpartum, breathing during lifting, awareness of PFM) and living conditions. Inclusion criteria for participants were being an adult woman of reproductive age (18–49 years), involved in carrying loads, permanently living in the project area, and having a social partner such as husband or mother-in-law from the same or neighboring household to support them informationally, practically or emotionally. This presupposes that the partners are present and cognitively able to support the participant. In the self-efficacy-only condition, two village sections were skipped because of COVID-19 cases, and women living in these sections were not included.

The sample size was estimated at $N = 300$ by an a priori power analysis for a repeated-measures analysis of covariance for three conditions with a desired power of >80%, a significance level of $\alpha = 0.05$, the assumption of medium effects (based on another study (Ernsting et al., 2015)), and allowing for an expected dropout rate of up to 20% from baseline to follow-up (Faul et al., 2009).

Figure 1 provides the participant flow. From each of the three villages, 100 women and the social partners they had selected were surveyed before and after the intervention, resulting in a total sample size of $N = 300$ dyads of women and social partners. The present paper focuses solely on the data from the women. Of the 300 women, 20 dropped out at follow-up, mostly because they were traveling at the time of the follow-up visit (see all reasons in Figure 1).

Measures

See Supplemental material for item wordings. We mostly used existing measures (Barber et al., 2001; da Rocha et al., 2012; de Jong et al., 2016; Grøn Jensen et al., 2022; Hagen et al., 2009; Moss-Morris et al., 2002; Pathak et al., 2018; Schwarzer et al., 2003; Schwarzer and Knoll, 2007) that were adapted to the local context and piloted within a mixed methods study in the study area (Tomberge et al., 2022). Items using unipolar Likert scales as answer options were augmented with a visual five-dot scale to support participants with low literacy (Harter et al., 2020). All items were translated and back-translated from English to Nepali and discussed and pretested in two villages not part of the analyses. The same measures were assessed at baseline and at 2-month follow-up.

Co-primary outcomes: Pelvic-floor-protective carrying behaviors. *Weight carried* was assessed by averaging two self-reported open questions about the average weight of water and other loads in kg (e.g. firewood), carried per trip in the preceding week.

Protective lifting techniques were assessed with an index that examined correctness and frequency of protective lifting, created from recommendations in physiotherapy literature (B??, 2004; Hagins et al., 2004; Kawabata et al., 2010; Sarno and Hameed, 2018). To assess correctness, the women were asked to lift a filled water container of the size they usually carry and then asked what they did with their pelvic floor and how they breathed during lifting using open questions with precoded answer options:

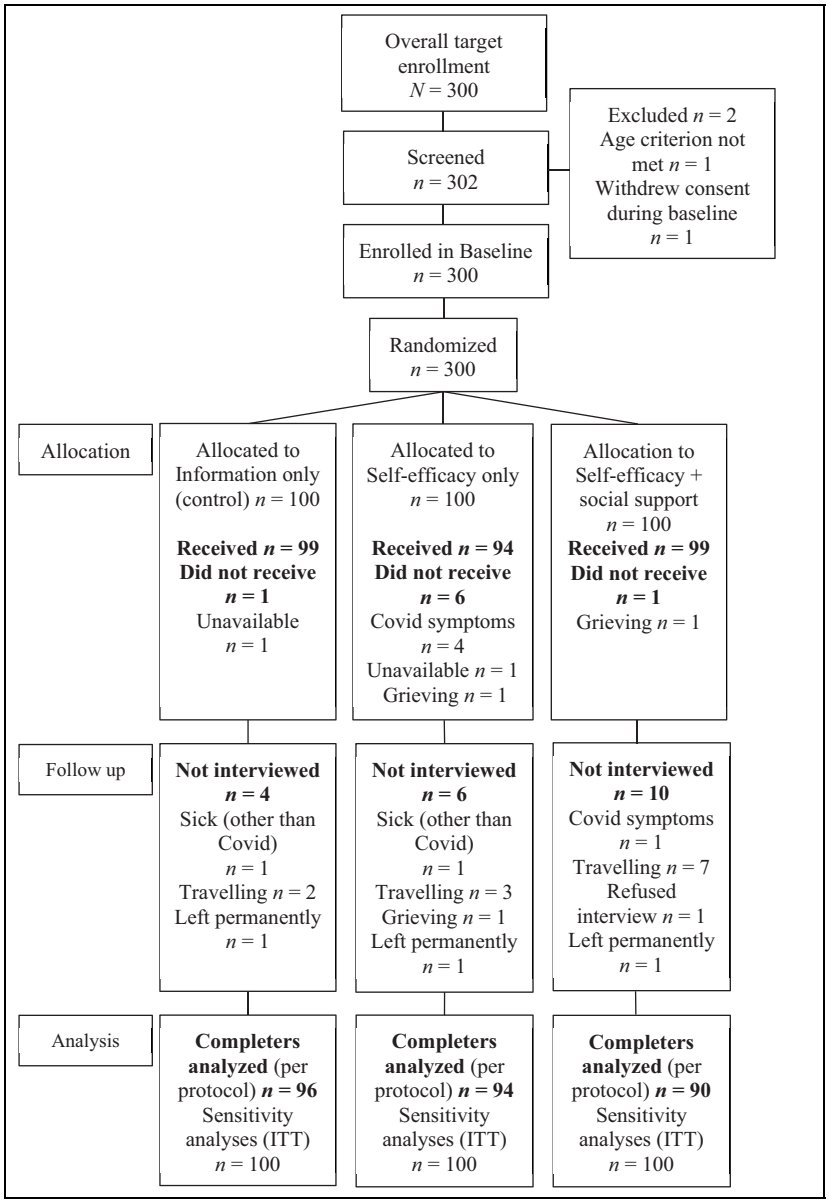

Figure 1. Participant flow chart.
ITT = Treating missing values with Intention-To-Treat.

0 = “inhale”; 1 = “exhale”, 0 = “hold breath”, 0 = “not aware of”; 0 = “other”. The frequency items referred to the proportion of times they used protective lifting in the last week, with answer options from 1 = “(almost) never (0%)” –5 = “(almost) always (100%)”. The index was calculated using the following formula: (Tightens PFM + exhales while lifting) × Mean frequency

(Frequency of tightening PFM when lifting in the last week; frequency of exhaling when lifting in the last week).

The index showed acceptable internal consistency of the four items ($\alpha = 0.67$), and high convergent validity: the self-reported breathing was strongly correlated ($r = 0.75$) with breathing observations made by the researchers during the behavioral demonstration.

Secondary outcomes. *Self-efficacy* in reducing weight carried and using protective lifting techniques was calculated from a mean of five items each ($\alpha = 0.91$–0.95; Schwarzer et al., 2003).

Social support for reducing weight carried and using protective lifting techniques was calculated from a mean of six items on informational, emotional, and instrumental received social support ($\alpha = 0.91$–0.94; Schwarzer and Knoll, 2007). Social support in using protective lifting techniques was assessed only at follow-up. We decided this after the pretest because women and others that might have supported them hardly knew about protective lifting at baseline, and were thus unable to report received support for this.

Carrying frequency per week. This was calculated by the product of self-reported carrying trips per day by days carried per week.

Physical health. We assessed pain in the pelvic/urogenital area with the mean of three items with the revised Faces Pain Scale and the Numerical Pain Rating Scale (Pathak et al., 2018; Sharma et al., 2017), symptoms of pelvic organ prolapse with The Pelvic Organ Prolapse Symptom Score (Hagen et al., 2009) and urinary incontinence (occurrence and frequency based on the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (Grøn Jensen et al., 2022). The impact of these symptoms during activities such as lifting and coughing was assessed based on the Pelvic Floor Impact Questionnaire (Barber et al., 2001). The physical health measures indicated acceptable to good internal consistency ($\alpha = 0.69$–0.75) except for pelvic organ prolapse and pain at follow-up ($\alpha = 0.60$).

Psychosocial wellbeing. This was assessed using the illness-related personal control ($\alpha = 0.73/0.77$), a subscale of the revised Illness Perception Questionnaire (Moss-Morris et al., 2002), quality of life (EUROHIS Quality of Life 8-Item Index, $\alpha = 0.83/0.85$; da Rocha et al., 2012) and one item on daily functioning (Functioning Rating Scale; de Jong et al., 2016).

Covariates. These included age, socioeconomic status calculated by income per household member, ethnicity, education and pregnancy status (pregnant or up to 3 months postpartum/neither of these).

Procedures

A research assistant unrelated to this project randomly allocated the villages to one of the three conditions by drawing lots. The allocation was concealed in sealed envelopes until the night before the intervention delivery. Participants were blinded to condition.

After obtaining approval from local leadership and presenting and discussing the study goal and general procedures of the study with local stakeholders and community health volunteers, six trained Nepali research assistants enrolled participants following the random route method (Hoffmeyer-Zlotnik, 2003). After obtaining participants' written informed consent by signature or thumbprint, two researchers simultaneously conducted the same structured computer-assisted personal interviews using tablets and structured behavioral observations with the women and their social partners. The interviews lasted 40–60 minutes on average (30–50 minutes interview + 5–

10 minutes observation). These included items to assess psychosocial attitudes, carrying behaviors and their health (details under measures). In the week after the baseline assessments, a trained health practitioner from a different team than the interviewers visited each household individually and delivered the assigned intervention, which lasted 10 (controls) to 30 minutes (social support intervention). After 2 months, the research assistants revisited their households for follow-up assessment. At the end of the follow-up visit, households were debriefed by revealing their assigned condition. In the absence of clear guidelines when to evaluate behavior change interventions, this 2-month interval was chosen to allow enough time for the women to try out the new behaviors and the social partners to support them after the intervention visit. Further, the 2-month interval allowed us to conduct the intervention and follow-up visits efficiently with the available research resources (e.g. transportation logistics to the different villages).

Interventions

Based on their assigned conditions, the participants received Behavior Change Techniques (BCTs) that promoted information, self-efficacy based on suggestions by Bandura (1977) or social support based on suggestions by Michie et al. (2013) and Scholz et al. (2020). All activities were delivered by health practitioners who were trained by the third author (see S2 for physiotherapy training details) in individual face-to-face household visits. A detailed overview of the intervention activities and corresponding BCTs can be found in Tables S3 and S4 in the Supplemental materials.

Participants in all conditions first received information on health consequences and pelvic-floor-protective carrying and practiced how to tighten the pelvic floor in sitting position as this was a prerequisite of protective lifting (BCTs 5.1 Information about health consequences; 4.1 Instruction on how to perform a behavior). This was supported with leaflets validated in rural Nepal (see Figures S6 & S7 for validated leaflet and Figure S5 for a leaflet designed specifically for this study; Caagbay et al., 2017, 2020). The information only condition received only these instructions. Subsequently, the intervention conditions received additional interventions according to their assigned condition.

Self-efficacy promotion. Self-efficacy was promoted by activities targeting the four sources of self-efficacy (Bandura, 1977): performance accomplishments, vicarious experience, verbal persuasion, and emotional arousal.

First, the practitioners invited the women to practice protective lifting and provided encouraging feedback (BCTs 8.1 Behavioral practice/rehearsal, 15.1 Verbal persuasion about capability; 2.2 Feedback on behavior). Second, the women were videotaped and then watched themselves on the video and identified which components of protective lifting they had applied successfully (BCTs 15.3 Focus on past success; 2.3 Self-monitoring of behavior). Third, the women were shown a video of a rural Nepali woman (role model, see Figure S9 for a screenshot of the video) carrying a reduced-weight load and using pelvic-floor-protective lifting techniques and were encouraged to do the same (BCTs 4.1 Instruction on how to perform the behavior; 6.1 Demonstration of behavior; 16.1 Vicarious reinforcement; 15.1 Verbal persuasion about capability). In the fourth activity, the women received a model of a woman, loads, and symbols of the pelvic floor and breath made of paper (see these symbols in Figure S8) and were encouraged to set up a scene of themselves carrying less weight and performing pelvic-floor-protective lifting (BCT 15.2 Mental rehearsal of successful performance). To enhance positive emotional arousal, the women were asked to draw a smiling face on the model (BCT 11.2 Reduce negative emotions). Finally, the practitioners read out a mental journey to further increase a relaxing

arousal (BCT 11.2 Reduce negative emotions). In the mental journey, the women imagined themselves standing in the field and then deciding to reduce the weight they carried and to practice protective lifting (BCTs 15.2 Mental rehearsal of successful performance; 15.1 Verbal persuasion about capability; 4.1 Instruction on how to perform the behavior). They were encouraged to inwardly repeat to themselves: "I am sure I can carry less weight [use protective lifting techniques]" (BCT 15.4 Self-talk).

Self-efficacy and social support promotion. The procedure and activities were exactly the same as in the self-efficacy condition with the difference that individual and dyadic techniques to promote social support were applied alongside self-efficacy (Michie et al., 2013; Scholz et al., 2020). Specifically, the women and their social partners received all the information and practiced self-efficacy activities together, this can be classified as a joint dyadic behavior change technique: Cooperative learning (Scholz et al., 2020). The social partners were instructed to support the learning process informationally and emotionally (Cross-over DBCTs: 15.1, Feedback on behavior; 3.2, Social support, practical; 3.3, Social support, emotional, see details in Table S3–S4). However, they did not receive support-specified skills training.

Data analyzes

Missing data at follow-up were treated using listwise deletion (Graham, 2009). However, we performed sensitivity analyses using Intention-To-Treat (ITT) replacing missing follow-up data by the baseline (Graham, 2009). Univariate outliers $M + -3$ SD were adapted to the next highest or lowest value within 3 SD for all variables (Tabachnick and Fidell, 1983). We performed an additional analysis without correcting outliers for symptoms of pelvic organ prolapse to account for women with strong symptoms.

To evaluate baseline group differences for all study variables (randomization check), we used ANOVAs with condition as independent variable and the baseline measures each as dependent variable or Chi-square test of equal frequencies for nominal variables such as ethnicity.

Main effect models

To investigate the intervention effects on weight carried and protective lifting we conducted repeated-measures ANOVAs with the two measurement points and the conditions as independent variables and each of the outcomes as dependent variables. Because our randomization check indicated group differences at baseline (see results section), we then decided to analyze group-by-time effects using planned contrasts with change scores (baseline score-follow up score) in univariate ANOVAs (van Breukelen, 2013). We used Helmert contrasts to compare information-only controls against the two intervention conditions (H1) and then compared self-efficacy against self-efficacy and social support (H2; Schad et al., 2020).

In order to investigate whether reduced weight carried related to increased carrying frequency, we examined correlations of change scores from the two measurement points for these two variables. To investigate time effects the preregistered secondary outcomes psychosocial wellbeing and physical health symptoms we conducted a repeated-measures ANOVA.

Mediation analyzes

To analyze whether self-efficacy or social support mediated the intervention effects on protective carrying behaviors (H3 and H4), mediation analyses were conducted using PROCESS in SPSS (Hayes, 2017). Change in self-efficacy and social support at follow-up were used as mediators of the effect of conditions on change in both protective carrying behaviors.

Sensitivity analyzes

To confirm the robustness of the findings, four sensitivity analyses were performed for the main effect models (H1 and H2): (1) Removing participants who did not receive the intervention from the data set, (2) removing multivariate outliers from the data set (residuals + − 2 SD), (3) ITT analysis, and (4) adding sociodemographic factors as covariates to the model.

All analyses were performed in IBM SPSS Statistics for Windows, Version 28.0 (IMB Corp, 2021); visualizations of effects were created in RStudio v 2022.07.01(R Core Team, 2022) using the ggplot2 package (Wickham, 2016), the interact_plot package (Long, 2021) and the ggpubr package (Kassambara, 2022).

Results

See Table S10 in the Supplemental materials for detailed sociodemographic data. The average household income of all women was 9168 NPR per month (~72 USD, SD = 62 USD), 45% of the women were illiterate or had informal education. Social partners were 32% husbands, 31% mothers-in-law, 10% female friends and neighbors, and 8% sisters-in-law or others. They were on average 48 years (SD = 16 years) old and 60% were not able to read and write or had informal education.

At baseline, 15% of women reported symptoms of urinary incontinence, and 14% reported often feeling one or more symptoms of pelvic organ prolapse. They carried 17 kg (SD = 8 kg) of water 13 times (SD = 9) per week and 27 kg (SD = 15 kg) of other loads 7 times (SD = 6) per week. Twenty-eight percent tightened the PFM, and 36% exhaled when demonstrating lifting; however, only 7% reported using one or both techniques at least half of the times they lifted loads at baseline.

Randomization check

Several statistical baseline differences emerged between conditions (see Tables S10 and S14 in the Supplemental materials). All conditions differed from one another in distribution of ethnicities. Women in the information-only control condition were older and had lower education and a higher proportion of Buddhists than Hindus than did the intervention conditions. Women in the self-efficacy-only condition had fewer children, carried on average 10 kg less weight per trip, and had higher self-efficacy in using protective carrying than the other two conditions. They further reported higher household income and received more social support in reducing weight carried than controls.

Intervention fidelity

Eight women did not receive the intervention. They differed from recipients at baseline secondary outcomes, having decreased ability in feeling their PFM [$t(291) = -5.77$; $p < 0.001$, $d = 0.3$], but higher injunctive norms (i.e. others' approval) [$t(8.40) = 3.28$; $p = 0.011$, $d = 0.25$] and lower perceived barriers to reducing weight carried [$t(8.06) = -2.60$; $p = 0.031$, $d = 0.3$].

In terms of participant's intervention comprehension and learning we found that women in all conditions increased their ability in feeling their PFM from baseline to follow-up (12%, medium effect: $\eta^2 = 0.06$) and were more likely to report a technique for tightening the PFM (24%, large effect: $\eta^2 = 0.25$). At follow-up, we asked the women which intervention activities they remembered (see descriptive statistics and group differences in Table S11). Women in the social support condition mentioned more protective lifting techniques correctly than women in the other two conditions ($p < 0.001$, medium effect: $\eta^2 = 0.25$) and remembered all self-efficacy activities more than women in the self-efficacy-only condition ($p < 0.001$–$p = 0.030$, small effects: $d = 0.4$).

Main intervention effects

An overview of descriptive statistics and group differences for co-primary outcomes is given in

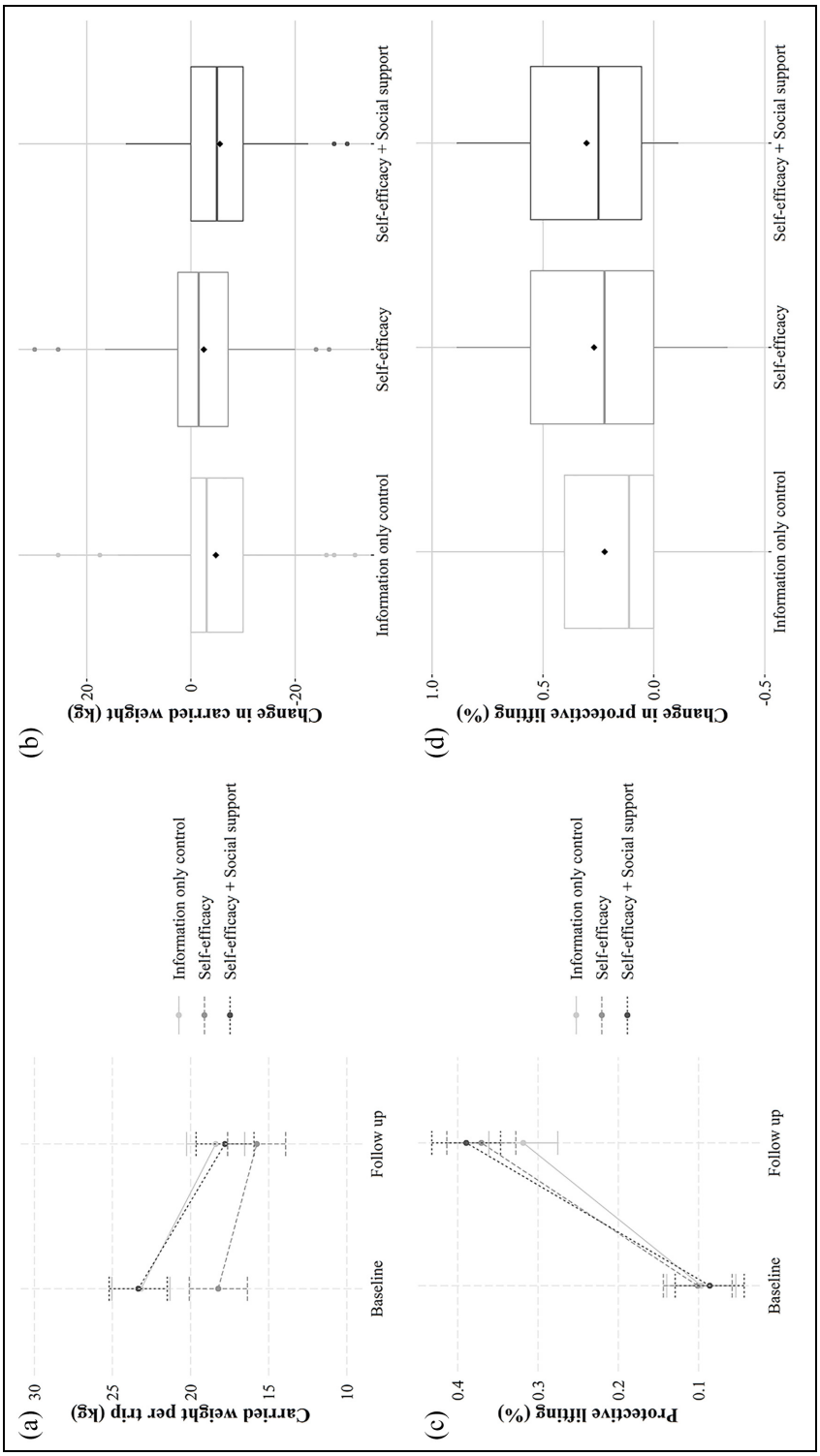

Figure 2. Intervention effects on protective carrying behaviors (co-primary outcomes). Plots (a and c) visualize time effects in protective carrying behaviors from baseline to follow-up. Plots (b and d) visualize change scores in the three conditions.

Table S12 and a visualization in Figure 2. All conditions significantly increased the use of protective lifting techniques by 23%–33% and decreased mean weight carried by 3–6 kg after the interventions (large time effects $\eta^2 = 0.49/0.20$).

Regarding the use of protective lifting techniques, effects of different conditions differed (small group by time effect: $\eta^2 = 0.02$). Planned contrasts revealed that the intervention conditions compared to controls showed 8.5% greater use, supporting H1a [$p = 0.013$, $d = 0.3$]. There was no added effect of self-efficacy and social support compared to self-efficacy, rejecting H2a [$t(277) = 1.20$; $p = 0.111$]. An exploratory analysis found that self-efficacy and social support increased lifting techniques by 10% more than controls [$t(277) = 2.53$; $p = 0.009$, medium effect: $d = 0.6$].

Effects of conditions on reducing weight carried also differed over time (small group by time effect: $\eta^2 = 0.03$). Planned contrasts indicated that, against H1b, the intervention conditions did not reduce weight more than information only [$t(277) = 0.52$; $p = 0.304$]. However, self-efficacy and social support reduced weight carried to a greater extent (3 kg more) than self-efficacy, supporting H2b [$t(277) = -2.65$; $p = 0.005$ (one-tailed), $d = 0.4$]. Exploratory analyses indicated that self-efficacy and social support did not reduce weight carried over information only [$t(277) = -0.89$; $p = 0.374$].

Sensitivity analyses for main effects. Overall, the results remained substantively unchanged after excluding data from participants who did not receive the intervention, removing multivariate outliers, or using ITT (See Table S12 for sensitivity analyses). The only except was a group-by-time interaction in the ANOVA, which did not remain robust for protective lifting when using ITT. Still, the planned contrast remained substantively unchanged ($p = 0.033$, $d = 0.3$). When adjusting for sociodemographic variables (see Table S13), the group-by-time effects for weight carried were no longer significant.

The role of self-efficacy and social support as mediators

We did not find group differences in changes to self-efficacy in reducing weight or using protective lifting. Thus, the condition for mediation was violated, and we rejected the mediation hypotheses for self-efficacy (H3). An exploratory analysis showed that the intervention did increase self-efficacy short-term, immediately after the intervention compared to controls ($M = 0.84/0.85$, $p < 0.001$).

Partly supporting H4, social support in using protective lifting techniques at follow-up was 24% higher in the self-efficacy intervention conditions than controls ($p < 0.001$, medium effect: $\eta^2 = 0.07$), and mediated the intervention effects on increased protective lifting techniques, with condition predicting social support ($B = 0.14$, $p < 0.001$) and social support predicting protective lifting ($B = 0.28$, $p < 0.001$), indirect effect $ab = 0.04$, 95%-CI [0.02, 0.07]. Comparing the self-efficacy + social support condition to controls, greater social support also explained increased protective lifting, with a stronger indirect effect $ab = 0.07$, 95%-CI [0.03, 0.14]. For weight carried, there was no evidence of mediation in the absence of group differences in changes in social support. It is noteworthy that social support in reducing weight significantly decreased by 8% from baseline to follow-up across all conditions ($p < 0.001$, $\eta^2 = 0.07$). There were no differences in social support depending on the social partner's role or gender but older partners supported less in carrying weight (see Appendix S10b)

Interventions effects on secondary outcomes

We did not find any group-by-time effects in secondary outcomes except for pelvic and

genital pain, which was reduced by 8% more in the self-efficacy and social support condition than in the self-efficacy-only condition (small effect: $\eta^2 = 0.02$). However, we found time effects for various secondary outcomes across all conditions (see Table S14 in the Supplemental materials for all preregistered variables). All women reduced carrying frequency of water by around 2.5 trips and other loads by around 1.5 trips per week over time (medium/small effect: $\eta^2 = 0.08/0.03$). Women who reduced carried weight to a greater extent showed greater reductions in their carrying frequency ($r = 0.08/0.22$, $p = 0.003/0.001$).

Regarding our research question on time effects on physical health, women in all conditions reported less urinary incontinence (small effect: $\eta^2 = 0.04$). Those who reported incontinence reported a reduced frequency of leaking urine within 1 week (large effect: $\eta^2 = 0.52$), but their perceived burden of incontinence symptoms did not change. All women decreased in symptoms of pelvic organ prolapse (-0.92 points, medium effect: $\eta^2 = 0.10$) and rated the impact of symptoms, if they had any, as 8% lower (large effect: $\eta^2 = 0.14$). The decrease in symptoms remained unchanged when not controlling for statistical outliers in symptoms (i.e. not adjusting women with high symptoms of pelvic organ prolapse to sample mean), (-1.0 points decrease in symptoms over time, medium effect: $\eta^2 = 0.09$). Regarding psychosocial well-being, all women on average increased 4% in illness-related control over pelvic organ disorders (large effect: $\eta^2 = 0.36$) and reported that carrying loads was on average 5% less of a burden for their daily functioning in other tasks at follow-up (small effect: $\eta^2 = 0.02$). No effect was found for quality of life.

Discussion

Our study provides first promising, quasi-experimental evidence for the increased effectiveness of self-efficacy and social support on protective carrying behaviors over giving information only. Women in the self-efficacy and the self-efficacy and social support conditions indicated more frequent use of protective lifting techniques compared to women receiving information only (H1a). Comparing women from the two self-efficacy intervention conditions, weight carried was only reduced when social support was also promoted (H2b). Finally, there were improvements in all conditions in behavior, health, and well-being, such as reduced symptoms of pelvic organ prolapse and perceived control over pelvic floor disorders.

All time effects on protective carrying were large. Group-by-time effects on protective carrying were small, except for the effect of self-efficacy and social support on protective lifting, which was medium sized. All time effects on protective carrying behaviors remained highly robust in the sensitivity analyses. The group effects remained robust in several sensitivity analyses. However, intervention effects did not remain robust when using ITT in the analysis for protective lifting or when controlling for sociodemographic variables for weight carried. Overall, these findings provide strong first evidence for the effectiveness of this behavior change intervention in promoting protective carrying behaviors and reducing the health risks of carrying heavy loads. Self-efficacy interventions may thus complement educational approaches to health behavior change and target the limited behavioral self-efficacy in populations with socioeconomic disadvantages that is often discussed (Greene and Murdock, 2013; Schüz et al., 2020; Tomberge et al., 2022, 2024).

Findings diverged on the benefits of the self-efficacy conditions for the two carrying behaviors. A possible explanation for this is that the behaviors may require different coping strategies (Carver et al., 1989). Protective lifting techniques can be chosen and applied by the women alone, but reducing weight carried may need the help of social partners if household needs for food and water supply are to be met

(Earth and Sthapit, 2002; Tomberge et al., 2022). Our social support intervention made this social resource available directly. Also, the finding that women did not increase carrying frequency when reducing carried weight can be an indicator for a social coping strategy rather than an individual one, for example, walking more times with less weight.

Against our expectations, our intervention effects were not explained by changes is self-efficacy. This is in line with some health interventions for self-efficacy and social support which have similarly achieved desired behavioral outcomes without changing self-efficacy (Allison and Keller, 2004; Hohl et al., 2016). Interestingly, we found a large increase in self-efficacy immediately after the intervention, supporting the validity of our intervention in promoting self-efficacy. However, this one-time intervention might not have been successful in maintaining self-efficacy over time.

In contrast, our mediation analyses indicated that social support explained the intervention effect on increased use of protective lifting techniques. Social support as a mediator of the effects in the intervention conditions is in line with the cultivation hypothesis. The cultivation hypothesis, which is often discussed together with the enabling hypothesis, suggests that self-efficacy facilitates social support such that more self-efficacious individuals are more likely to reach out for help. This in turn explains behavioral health outcomes (Schwarzer and Knoll, 2007).

While the intervention effects on increased use of protective lifting was explained by social support, the mechanisms of the intervention of increased reduction of carried weight remain unexplained by the assumed mechanisms of self-efficacy and social support. An alternative explanation may be that women in the social support condition remembered significantly more self-efficacy activities than women in the self-efficacy condition without support. This may simply indicate that the intervention itself was more engaging due to the interaction with the social partner, but another possibility is that the social exchange about protective behaviors helped women to remember (Scholz et al., 2020).

Strengths and limitations

This study is the first to quasi-experimentally test the effect of self-efficacy and social support on women's health behavior in a low-resource setting which is proposed by the enabling hypothesis. It is also the first to examine carrying loads from a health behavior change perspective and emphasize the importance of this neglected research field to promoting women's health in low-resource settings. Our intervention materials were developed in close discussion with local researchers and practitioners and provide a culturally adapted intervention to promote protective carrying behaviors tailored for women living in rural Nepal. These materials can now be used and adapted for further evidence-based health prevention campaigns and intervention studies in similar settings.

There are also some limitations and avenues for future research. The non-randomized study design contributed to systematic group differences in sociodemographic as well as behavioral factors. A cluster-randomized design would have avoided this risk, but such a design requires large samples and corresponding resources and would not have been warranted at this early stage of research. That said, the results of our study provide evidence that the interventions are feasible and promising and should be tested in a cluster-randomized controlled trial as a next step. An additional limitation of this study is that we did not apply a factorial design and were therefore unable to fully investigate all effects and mechanisms of all combinations of providing information, self-efficacy, and social support. Future study designs may include a social support only condition to address this limitation. Further, the generalizability of our results needs to be tested in similar populations that present behavioral

risks for pelvic floor health, such as heavy working and lack of postpartum PFM exercise (Caagbay et al., 2020; Geere et al., 2010; Harvey, 2003).

Conclusions

Our study provides promising evidence of the importance of self-efficacy and social support in a low-resource setting. Health behavior change interventions for pelvic-floor-protective behaviors, such as protective carrying can enable women in low-resource settings and demanding environments to care for their pelvic health independently and help prevent pelvic floor muscle disorders.

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Author contributions

VMJT: funding acquisition, conceptualization, methodology, Software, investigation, data curation, formal analysis, visualization, writing—original draft preparation AS.: conceptualization, supervision, project administration, resources, and writing—review and editing, HL: conceptualization, supervision, resources and writing—review and editing; AK investigation, project administration; CS: investigation, data curation, formal analyses and writing—review and editing; RM: conceptualization, and writing—review and editing; JI, conceptualization, methodology, resources, supervision, validation and writing—review and editing.

Data sharing statement

All data generated or analyzed during this study are included in their entirety in the open science repository https://osf.io/73xhk/?view_only=1151ff07e813415eb553b92d0f5ce80b. Ethics approval, participant permissions, and all other relevant approvals were granted for this data sharing

Declaration of conflicting interests

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Ethics approval

The study was approved by the Ethical Review Committee of the Nepal Health Research Council [514/2021] and the Ethical Board of the University of Bern, Switzerland [2021-10-00005]. All procedures were in accordance with the ethical standards of the institutional and national research committees and with the 1964 Helsinki declaration and its later amendments. This article does not contain any studies with animals.

Informed consent

All participants provided written informed consent prior to their interviews and observations. Potential study participants who could not sign their names were permitted to indicate consent with a thumbprint.

Pre-registration

This trial was preregistered: https://clinicaltrials.gov/ct2/show/record/NCT05154006

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Supplemental material

Please see online supplementary material for measures, intervention materials, and detailed tables on sample characteristics, intervention fidelity, sensitivity analyses and further preregistered, secondary outcomes.

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