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1        **The effect of a mindfulness and motivational interviewing-oriented physical-**  
2        **psychological integrative intervention for community-dwelling spinal cord injury**  
3        **survivors: a mixed-methods randomized controlled trial**

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25

26    **Abstract**

27    **Objective:** To evaluate the feasibility, acceptability, and efficacy of a mindfulness and  
28    motivational interviewing-oriented physical-psychological integrated intervention in  
29    community-dwelling spinal cord injury (SCI) survivors.

30    **Design:** A mixed-methods randomized controlled trial.

31    **Setting:** Local organizations of handicapped in Hong Kong.

32    **Participants:** Community-dwelling adults with SCI (N = 72).

33    **Interventions:** Participants in the intervention group (n = 36) received video-guided  
34    exercise for daily practice and online group psychological (mindfulness and  
35    motivational interviewing-oriented) weekly sessions for eight weeks. Participants in the  
36    control group (n = 36) received an eight-week online group didactic education on  
37    lifestyle discussions and general health suggestions.

38    **Main Outcomes Measures:** Primary outcomes included quality of life, physical  
39    activity, depression, and chronic pain. Secondary outcomes included exercise self-  
40    efficacy and mindfulness. Outcomes were measured at baseline, post-intervention, and  
41    three-month follow-up. Focus-group interviews were conducted post-intervention.

42    **Results:** The recruitment, retention, and adherence rates were 84.7%, 100%, and  
43    98.6%, respectively. The intervention showed significant positive effects on preventing  
44    declines in quality of life at three-month follow-up [Cohen's  $d = 0.70$  (0.22, 1.18)].  
45    Positive trends manifested in physical activity, depression, chronic pain, and exercise  
46    self-efficacy. Three qualitative categories were identified: subjective improvements in  
47    exercise, physical, and social well-being; perceived changes in mindfulness and mental  
48    well-being; and intervention facilitators and barriers.

49    **Conclusions:** The mindfulness and motivational interviewing-oriented physical-  
50    psychological integrated intervention is feasible and acceptable. The significant

prolonged effect in maintaining quality of life and positive impacts on physical and psychosocial well-being indicate its value to address major health challenges of community-dwelling SCI survivors.

**Keywords:** spinal cord injuries; quality of life; mindfulness; motivational interviewing; exercise

**Abbreviations:** SCI, Spinal cord injury; RCT, randomized controlled trial; MVPA, moderate-to-vigorous physical activity

Spinal cord injury (SCI) results in irreversible loss of motor and/or sensory function partially or completely below the level of the injury site <sup>1</sup>. There were an estimated 20.6 million SCI cases globally <sup>2</sup>. Currently, thousands of SCI survivors live in the community in Hong Kong <sup>3</sup>. They experience a significant decline in the quality of life compared to the general population due to permanent disabilities and varied biopsychosocial complications <sup>4</sup>. Physical inactivity, depression, and chronic pain are major health challenges undermining the quality of life of community-dwelling people with SCI <sup>5</sup>.

A systematic review of activity-based interventions for SCI individuals showed positive effects in addressing physical inactivity <sup>6</sup>. However, limited high-quality randomized controlled trials (RCTs) have addressed the needs of community-dwelling people with SCI, partly due to transportation barriers <sup>7</sup>. Tele-exercise interventions are recommended by two pilot trials to improve physical activity among community-dwelling SCI survivors <sup>8,9</sup>. Evidence has also identified improvements in depression, chronic pain, and quality of life following activity-enhanced interventions in the SCI

population <sup>6</sup>. Furthermore, psychological skills like motivational interviewing are encouraged to enhance adherence to physical activities <sup>9</sup>. This implied that remote physical exercises incorporating motivational interviewing may be a promising modality to address physical inactivity and improve the well-being of community-dwelling SCI survivors.

Mindfulness, as a mind-body intervention, provides an effective non-pharmacological alternative for managing depression and chronic pain through cultivating acceptance of emotions and behaviours <sup>10, 11</sup>. A recent review of five mindfulness interventions reported significant reductions in depression and pain among SCI individuals <sup>12</sup>. However, the conclusions are tentative due to a small number of studies and the moderate-to-high risk of bias (e.g., non-random and non-controlled). RCTs are needed to examine the effects of mindfulness interventions on improving depression and chronic pain in SCI survivors. Mindfulness interventions are also recommended for improving the quality of life through the mediation of reduced depression and chronic pain <sup>13, 14</sup>.

While there is a large group of community-dwelling SCI survivors in Hong Kong, the availability of community-based rehabilitation is still limited <sup>15</sup>. In particular, research on the effects of interventions integrating both physical exercises and psychological skills jointly in promoting the overall well-being of community-dwelling SCI survivors is scarce <sup>8, 16</sup>. This is the first RCT to evaluate the feasibility and effectiveness of a mindfulness and motivational interviewing-oriented physical-psychological integrative online group intervention on community-dwelling SCI survivors in Hong Kong. A qualitative study was employed to explore the intervention acceptability and to understand the mechanism of intervention effects. The findings

would provide high-quality evidence for community healthcare workers to conduct comprehensive health programs for people with SCI.

## **Methods**

### **Design**

We adopted a sequential mixed-methods design that consisted of an open-label, two-arm RCT and a qualitative study. The study protocol was published<sup>15</sup>. The trial was registered in ClinicalTrials.gov (NCT05535400) and approved by the Institutional Review Board. Written informed consent was obtained from all participants.

### **Participants**

Participants were recruited from the Hong Kong Direction Association for the Handicapped, the Hong Kong Federation of Handicapped Youth, and other local centers from October 2022 to June 2023 by a trained research assistant. Inclusion criteria: 1) adults ( $\geq 18$  years old) living in the community with SCI for over 6 months; 2) complete injury at the C6 or below or incomplete injury at any level allowing arm movement for exercise; 3) wheelchair use over 2 hours/day; 4) accessible to Zoom software; and 5) Cantonese speaking and informed consent. Exclusion criteria: 1) physically active ( $>150$  minutes/week); 2) having significant cognitive impairment (medical records or The Cantonese Mini-Mental State Examination<sup>17</sup> score  $<18$ ) or any level of brain injury; 3) having hearing, vision, and verbal communication problems; and 4) medically unfit for or currently engaging in exercise/psychological program. To estimate a between-group effect, considering a 20% attrition rate, a small standardized effect size of 0.25 with 80% power, and a two-sided 5% significance, each study group

required 36 participants<sup>18</sup>. Qualitative focus-group interviews were conducted post-intervention with purposive sampling until data saturation was met<sup>19</sup>.

## **Randomization and allocation**

Eligible participants were randomly assigned to the intervention or control group using the randomization service at sealedenvelope.com by an external administrator. Random block sizes were used for group balance. Participants could not be blinded to group allocation due to the intervention nature and were reminded to keep it confidential to prevent contamination.

## **Intervention**

The intervention included physical exercise and psychological intervention sessions. Participants practised physical exercises including mobilization, strength, and aerobic exercise daily for eight weeks, following a 25-minute video developed by two experienced physiotherapists. Eight-week psychological interventions were conducted in online group (7–12 participants) sessions, lasting 60–75 minutes/week. The psychological intervention (see Appendix for details) began with motivational interviewing skills (e.g., empathizing) to promote exercise adherence. Participants' readiness for exercise was discussed<sup>9</sup>. Mindfulness training, adapted from the practice guideline 'mindfulness for health'<sup>20</sup>, was followed. Participants received mindfulness practice videos for home use. The intervention was led by a social worker with over 10 years of work experience, certification from the International Mindfulness Teachers Association, and training in motivational interviewing. The online sessions were video-recorded, and minutes were generated for review by a senior researcher (DB) with expertise in motivational interviewing and mindfulness to ensure fidelity. The control

group received online group didactic education on lifestyle discussions and general health suggestions facilitated by a trained research assistant with a Master's degree in psychology, lasting around 30 minutes/week for eight weeks.

## **Measures**

A trained research assistant collected data self-reported by participants at baseline (T0), post-intervention (T1), and 3-month follow-up (T2).

**Feasibility and acceptability.** Feasibility was assessed by the recruitment period, recruitment rate, and retention rate. Acceptability was assessed by the adherence rate, adverse events, the Client Satisfaction Questionnaire (Cronbach's  $\alpha=0.94$ )<sup>21</sup>, and online focus-group interviews post T1 (participants who improved most and least from T0 to T1 in physical activity assessed by the objective accelerometer).

**Demographics and medical history.** Age, gender, education level, marital status, employment status, household income, injury level and duration, and medicine history.

**Primary outcomes.** Considering the significant roles of physical activity, depression, and chronic pain in determining the quality of life among people with SCI<sup>5, 6, 13, 14</sup>, our team identified quality of life as an additional crucial primary outcome, which differs from our original study protocol.

**Quality of life** was assessed by the World Health Organization Quality of Life Brief Scale with one overall single item (range 1–5) and four subscales<sup>22</sup>. Higher scores indicate a better quality of life. The scale showed satisfactory reliability in the SCI population (Cronbach's  $\alpha=0.805$ )<sup>11</sup>.

**Leisure-time moderate-to-vigorous physical activity (MVPA)** was assessed using the Fitbit Inspire 2 (Fitbit, Inc)<sup>a</sup> wristband accelerometer<sup>23, 24</sup>. A minimum of four days/week ( $\geq 10$  hours/day) of Fitbit usage data was considered valid<sup>25</sup>. The

average time reaching the MVPA heart rate zone per valid day was multiplied by 7 to adjust for valid days<sup>26</sup>. The MVPA heart rate zone is 64%–93% of the maximum heart rate<sup>27</sup>. The maximum heart rate is determined as 220 minus age years for paraplegia<sup>28</sup> and 130 for tetraplegia<sup>29</sup>.

**Depression** was assessed by the Patient Health Questionnaire (Chinese version Cronbach's  $\alpha=0.91$ )<sup>30</sup>. Threshold total scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression, respectively.

**Chronic pain** was assessed by the Numerical Pain Rating Scale from 0 (no pain) to 10 (the most imaginable pain), with satisfactory test-retest reliability (intraclass correlation coefficient=0.99)<sup>31</sup>.

#### ***Secondary outcomes***

**Exercise self-efficacy** was evaluated using the Self-efficacy for Exercise scale (Chinese version Cronbach's  $\alpha=0.90$ )<sup>32</sup>. A higher average score indicates greater exercise self-efficacy.

**Mindfulness** was evaluated by the Five-Facet Mindfulness Questionnaire (Chinese version Cronbach's  $\alpha 0.83$ )<sup>33</sup>. Higher total scores indicate higher levels of mindfulness.

#### **Data analysis**

All quantitative data were analyzed using IBM SPSS 26 and the RStudio. Intention-to-treat analysis was performed using last-observation-carried-forward for missing data<sup>34</sup>. Cohen's  $d$  was used for effect size estimation considering a small sample size<sup>35</sup>. Intervention effects were analyzed using the generalized estimating equation model, controlling for baseline scores and covariates identified by randomized testing between groups at baseline ( $p<0.05$ )<sup>36</sup>. Qualitative data were content analyzed<sup>37</sup>. Interview data were coded independently by two authors and discussed by our team.



199

## 200 **Results**

### 201 **Recruitment and participant flow**

202 Recruitment occurred between October 2022 and January 2023. Follow-up  
203 completed in June 2023. Figure 1 illustrates the study flowchart following the  
204 Consolidated Standards of Reporting Trials statement. Seventy-two out of 85 eligible  
205 subjects consented (84.7% recruitment rate) and were allocated. All 72 participants  
206 completed the study (100% retention rate). For the 8-session intervention group, two  
207 out of 36 discontinued the last two sessions due to injury incidents (98.6% adherence  
208 rate). No direct intervention-related injuries or other adverse effects were reported.

209

### 210 **Baseline data**

211 Table 1 presents participants' characteristics at baseline. Among 72 participants,  
212 the mean age was 57.61 (SD=8.67) years; around half of them were female (55.6%)  
213 and married (58.3%); and the majority were unemployed (73.6%). They reported 24 (9,  
214 46.75) years post-SCI and mostly paraplegia (88.9%). The overall quality of life was  
215 3.15 (SD=0.76). Weekly leisure-time physical activity was 355.25 (136.00, 732.00)  
216 minutes/week. Participants reported a minimal level of depression (median=4) and a  
217 moderate level of chronic pain (mean=4.3). Exercise self-efficacy was 3.53 (SD=1.84)  
218 and mindfulness was 124.67 (SD=13.53). Significant between-group differences were  
219 found for years post-SCI ( $p=0.001$ ), mental health medication ( $p=0.020$ ), and pain  
220 medication ( $p=0.009$ ), which were controlled in intervention effect tests.

221

## Intervention satisfaction and effectiveness estimation

Compared to the control group, the intervention group was significantly more satisfied with participation [23.53 (SD=3.18) vs 21.78 (SD=2.71),  $t=2.513$ ,  $p=0.014$ ]. Table 2 displays the intervention effects between groups and Figure 2 provides graphical representations. The significant interaction effect ( $p=0.005$ ) on the overall quality of life was identified. The intervention showed significant positive effects on preventing declines in the overall quality of life at T2 ( $p=0.001$ ), with a medium effect size (Cohen's  $d=0.70$ ). Two domains, psychological health (Cohen's  $d=0.56$ ) and social relationships (Cohen's  $d=0.67$ ), also observed significant between-group differences at T2 with medium effect sizes.

Despite non-significant intervention effects being identified for other outcomes, we observed an initial increased leisure-time physical activity in the intervention group at T1 and then a decrease at T2. In contrast, the control group experienced a continuous decrease. Both depression and chronic pain increased at T1 and then decreased at T2 in the intervention group. A significant group effect was found for exercise self-efficacy ( $p=0.020$ ).

## Qualitative results

Table 3 shows 15 interviewees' characteristics in four groups. Table 4 displays the categories and example quotes from interview data.

### Category 1: Subjective improvements in exercise, physical, and social well-being

***Subjective improvements in exercise.*** Participants perceived increased motivation to engage in exercises due to reminders, guidance, and peer accompaniment within the group.

247 "The group reminded me to do exercises. I feel  
248 motivated and more active to do it." (G2P1)

249 "With someone leading and guiding us, motivates me  
250 to do exercise properly." (G1P3)

251 "Yes, do exercises together, the motivation will be  
252 greater." (G4P1)

253 ***Improved physical and social well-being.*** Participants perceived reduced pain from  
254 aerobic exercises and relieved pain disturbance by adopting mindful coping skills.  
255 Some participants also improved social relationships.

256 "Doing aerobic exercise helps reduce pain and  
257 discomfort." (G4P1)

258 "I learned to cope with pain by accepting it and taking  
259 slow, deep breaths." (G4P3)

260 "I know each group member well and trust each  
261 other." (G2P3)

262

## 263 **Category 2: Perceived changes in mindfulness and mental well-being**

264 ***Improved mindfulness skills.*** Following the intervention, participants reported an  
265 improvement in mindfulness practice and skills including increased acceptance,  
266 awareness, being non-judging, and non-responsive.

267 "We were suggested to accept happy or unhappy  
268 things. I have become more aware of observing and  
269 feeling." (G1P2)

270 "I learned to form a non-judgmental mindset ... be  
271 more comprehensive and less subjective." (G2P5)

272 “I learned to avoid aggravating my emotions further”

273 (G2P3)

274 ***Improved mental well-being.*** Participants reported experiencing improvement in  
275 mental well-being. Some of them obtained a peaceful status and release from negative  
276 emotions through mindful practices.

277 “I used to be upset about my dad’s mental condition.

278 Now I am calmer when I accept it and avoid judging.”

279 (G2P1)

280 “I have learned to release negative emotions by deep

281 breathing exercises.” (G4P3)

282

### 283 **Category 3: Intervention facilitators and barriers**

284 ***Intervention facilitators.*** Participants identified several facilitators that contributed to  
285 their engagement in the intervention, including positive atmosphere, group interactions,  
286 and the perceived benefits.

287 “You (the intervention provider) created such a great

288 atmosphere, we felt enjoyable.” (G1P1)

289 “The sharing session motivated me to join in the group

290 activities.” (G4P3)

291 “The group is positive and helped me learn to relax.

292 The listening and sharing are good.” (G4P4)

293 ***Intervention barriers.*** Participants reported encountering certain barriers to practicing  
294 the intervention, including the duration/timing of sessions, competing demands on time,  
295 and injuries unrelated to the study intervention.

296 “I prefer to have longer sessions in evening. One hour  
297 is not enough.” (G3P1)

298 “I used to exercise regularly before. After the end of  
299 this program, I was occupied with other activities.”  
300 (G2P5)

301 “I got injured from a burn accident and was absent  
302 from the last two sessions.” (G1P3)

303

#### 304 **Discussion**

305 This study assessed the feasibility, acceptability, and efficacy of a mindfulness and  
306 motivational interviewing-oriented physical-psychological integrated online group  
307 intervention for community-dwelling SCI survivors in Hong Kong. Overall, the  
308 intervention was both feasible and acceptable and demonstrated significant positive  
309 effects on quality of life. Qualitative findings revealed that participants valued this  
310 integrated intervention, which facilitated their physical and psychosocial well-being.  
311 Our study provides initial evidence supporting the use of this intervention as a novel,  
312 feasible, and positive online group intervention addressing the well-being of  
313 community-dwelling SCI survivors.

314 This study achieved a high recruitment and retention rate, indicating the excellent  
315 feasibility of this program and the willingness of SCI individuals to participate. It is  
316 challenging to recruit participants with physical disabilities, especially those living in  
317 the community<sup>8, 38</sup>. The high study feasibility can be attributed to the online group  
318 modality and the trained intervention provider who was skilful in retaining participants.  
319 The intervention group showed high adherence and greater satisfaction compared to the

control group. Qualitative data suggests that the supportive group climate and perceived benefits of the intervention contributed to its excellent acceptability.

The intervention demonstrated a prolonged positive effect on maintaining quality of life at the three-month follow-up, in contrast to the significant declines observed in the control group. This finding was consistent with earlier activity-based interventions for SCI survivors <sup>39</sup>. Our qualitative findings further support the improved physical fitness and comfort following home-based aerobic exercises. Additionally, the psychological intervention sessions of this study were particularly beneficial in promoting psychological and social well-being through mindful relaxation and group interaction. With the physical-psychological integrated online group intervention, this study offers a comprehensive approach to maintaining and promoting the overall quality of life for community-dwelling SCI survivors.

The intervention did not yield significant improvements in physical activity, which contrasts with a trial utilizing physical activity counselling with psychological skills <sup>9</sup>. The conflicting findings might be attributed to the use of different outcome measurements. We employed an accelerometer instead of a self-report tool, which is less subject to reporting bias <sup>40</sup>. Interview participants reported active engagement in exercises during the intervention but decreased engagement during the follow-up. This suggests that extending the intervention duration or offering short weekly top-up sessions may help maintain or enhance its effect. Notably, the intervention contributed to higher exercise self-efficacy relative to the control group at follow-up, likely due to motivational interviewing techniques used to enhance exercise motivation <sup>9</sup>. Our qualitative findings also indicated that coach guidance and peer accompaniment facilitate physical activities, suggesting a peer coach-based program to maintain sustainable effects.

Interestingly, both the level of depression and chronic pain were not observed to immediately improve post-intervention but were relieved at the three-month follow-up. The lack of significant improvements might be related to the low levels of depression and chronic pain reported at baseline, which may limit the potential for further improvements<sup>12, 41</sup>. Another possible explanation can be attributed to the cumulative effects on mental health and chronic pain that may require time to manifest during the follow-up period<sup>42</sup>. Despite the statistical insignificance, qualitative data supported that mindfulness skills such as acceptance, non-judging, and deep breathing exercises contributed to a peaceful mindset and mental well-being. Moreover, two potential therapeutic components of the intervention for pain management were suggested, including relieving pain intensity through aerobic exercises and experiencing less pain disturbance following the adoption of mindful skills such as acceptance.

## **Limitations**

Several limitations should be acknowledged. The relatively small sample size might hinder detecting significant changes in some of the outcomes with very small effect sizes, and limit the external validity of the study findings. The study findings, based on the SCI sample with relatively low depression and chronic pain, may limit generalizability to more severe cases. Measurements were mainly self-reported, and therefore assessor-blinding was not adopted, increasing the risk of bias. The medium length of follow-up also limits the evaluation of long-term effects. Additionally, different online session periods between groups may introduce variability in the outcomes. Future clinical trials with a larger sample size, objective measurements, long-term follow-up assessments, and comparable between-group contact time are recommended to enhance the validity of study findings. Nevertheless, this study

provided evidence supporting community healthcare workers in designing comprehensive health programs for SCI survivors. Future health programs are encouraged to integrate both physical exercises and psychological interventions (i.e., mindfulness and motivation interviewing) to address the overall well-being of SCI clients. The home-based online group intervention is advantageous in overcoming transportation barriers and may increase adherence for community-dwelling residents. Experienced SCI survivors can be trained as peer coaches facilitating the sustained implementation of the program for long-term benefits.

## **Conclusions**

The mindfulness and motivational interviewing-oriented physical-psychological integrative intervention was found to be feasible and acceptable, resulting in significantly prolonged prevention of deteriorating quality of life for community residents with SCI. However, positive impacts of the intervention on physical and psychosocial well-being were indicated by qualitative findings. Clinical trials with larger sample sizes and long-term follow-ups are recommended for further examination of the effects of the intervention.

## **Conflict of interest**

None.

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## **Data availability**

The data that support the quantitative and qualitative findings of this study are available from the corresponding author upon reasonable request.

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## Suppliers

<sup>a</sup> Fitbit Inspire 2 (Fitbit, Inc).

## Figure legends

Figure 1. Study flowchart.

Figure 2. Graphical presentations of intervention effects between groups.