Published in final edited form as:

Disabil Health J. 2020 January ; 13(1): 100842. doi:10.1016/j.dhjo.2019.100842.

Differences among participants' response to a wellness intervention for individuals with spinal cord injuries

Stephanie L. Silveira, PhD^{1,2}, Tracey A. Ledoux, PhD¹, Craig A. Johnston, PhD¹, Claire Kalpakjian, PhD³, Daniel P. O'Connor, PhD¹, Michael Cottingham, PhD¹, Ryan McGrath, PhD⁴, Denise Tate, PhD³

¹Department of Health and Human Performance, University of Houston, Houston TX, USA

²Department of Physical Therapy, University of Alabama at Birmingham, Birmingham, AL, USA

³Department of Physical Medicine and Rehabilitation, University of Michigan, Ann Arbor, MI, USA

⁴Department of Health, Nutrition, and Exercise Sciences, North Dakota State University, Fargo, ND, USA

Abstract

BACKGROUND—Individuals with spinal cord injuries (SCI) often struggle with lifestyle adjustment following injury. Effective wellness interventions may aid in improving quality of life; however, treatment response heterogeneity is a concern for behavioral interventions.

OBJECTIVE—To identify differences among adults with SCI who were responders and non-responders in a wellness intervention.

METHODS—There were 29 persons with SCI who received a wellness intervention. Participants engaged in six in-person workshops over a 3-month period, led by wellness experts with peer mentors available. Individual intervention participant change was compared to the mean among control group participants target outcomes variables (i.e., satisfaction with life, self-efficacy for health practices, secondary conditions, health promoting behaviors, and perceived stress) to classify responders versus non-responders.

RESULTS—Of the 29 participants, 18 who completed the intervention were classified as responders and 11 were non-responders. The mean age was 43.2 ± 11.2 years, and years post-injury were 12.0 ± 9.8 . Decision tree regression analysis for demographic variables and injury characteristics showed that single/divorced participants were more likely to not respond to the intervention (52%), compared to married participants (17%). Further, participants who were single/divorced and 50 years old were more likely to not respond to the intervention (62%) than those who were older (25%).

CONCLUSIONS—Single/divorced individuals with SCI may respond differently to behavioral wellness interventions than married individuals. Additionally, the effects of age on treatment response in behavioral interventions should be further examined. Identifying non-modifiable

Corresponding Author: Stephanie L. Silveira, PhD, Department of Physical Therapy, University of Alabama at Birmingham, 3810 Ridgeway Dr., Birmingham, AL, 35209, Tel: 205-975-1306, ssilveira@uab.edu.

Conflict of Interest: No potential conflict of interest was reported by the authors.

factors related to response heterogeneity may help guide the creation of tailored interventions specific to patient characteristics.

Keywords

Behavior; Health; Quality of Life; Spinal Cord Injuries; Rehabilitation

INTRODUCTION

Wellness interventions aim to enhance quality of life (QOL) by providing resources and targeting modifiable behaviors such as nutrition, physical activity, and stress management.¹ The efficacy of an intervention is generally evaluated by comparing mean group differences; however, there is often inter-individual variability in treatment response (i.e., response heterogeneity) that is important for understanding those who significantly benefit from interventions. Response heterogeneity has been examined in some clinical trials. For example, in one study of adults with multiple sclerosis, the effect of a physical activity behavioral intervention significantly varied by disease characteristics (e.g., disability status), and other studies report that demographic characteristics (e.g., age and sex) are associated with response to exercise training.²⁻⁴ Assessment of individual differences in treatment response to behavioral interventions, including wellness interventions, should be emphasized as clinicians can then recommend interventions to individuals with particular non-modifiable characteristics.

Individuals with spinal cord injuries (SCI) may benefit from wellness interventions to aid in community adjustment following injury. Few wellness interventions for individuals with SCI and other disabilities have been developed to improve health behaviors and satisfaction with life (SWL). Generally, these programs seem to improve health-related quality of life (HR-QOL), mobility, mental health, self-efficacy, physical well-being, and general QOL.⁵⁻⁹ These interventions often report null results or “positive trends” in group means. The lack of group-level differences may be due to large individual variation in response. Identification of response heterogeneity is vital in assessing who will benefit from interventions as different modes of delivery or behavior change strategies may be appropriate for subgroups who share unique qualities.

Well on Wheels was a pilot wellness intervention developed specifically for individuals with SCI. The intervention was created using social cognitive theory (SCT) concepts aimed at improving wellness in individuals with SCI using evidence-based behavior change strategies.¹⁰ Targeted behaviors for change (i.e., nutrition, lifestyle management, secondary conditions, and physical activity) in the intervention were derived from Stuijbergen’s model of QOL in individuals with chronic disabling conditions.¹¹ This model explains a large portion of variance in QOL for individuals with disabling conditions, thereby providing strong evidence for targeting chosen factors associated with wellness following SCI.¹¹ Preliminary analyses of *Well on Wheels* conducted by Zemper et al.¹² from baseline to seven months post-intervention demonstrated no between group (control versus intervention) differences. However, stringent analyses were not conducted to examine which participants significantly benefitted from the intervention.

The purpose of this study was to address treatment response heterogeneity by identifying participants who did and did not respond to the *Well on Wheels* intervention and the non-modifiable qualities shared by those groups (i.e., “responders” versus “non-responders”). We hypothesized that demographic variables (i.e., age, sex, marital status, employment, and education) and injury characteristics (i.e. injury completeness, years post-injury, and injury level) would identify qualities of participants who would differentially respond to the intervention. Understanding the characteristics of those who do not respond to interventions in particular, can aid researchers in identifying subgroups who may require alternate intervention strategies. Demographics and injury characteristics can also provide clinicians an easy method for screening and referrals to programs. The study of response heterogeneity in wellness interventions fits in the broader context of precision medicine, which calls for tailored and optimized interventions addressing each patient’s unique needs.

METHODS

Participants

A secondary analysis from participants who were randomized into the *Well on Wheels* intervention group was performed. Those who completed baseline and three-month post-intensive phase of the intervention were included in analyses. Inclusion criteria for enrollment were: SCI of C5 and below, American Spinal Injury Association (AIS) Impairment Classification Scale A-D, 18–80 years of age, and at least 1 year post-injury. Exclusion criteria included: diagnosis of cognitive deficits preventing learning and carryover, medical problems that could impose a health risk, and primary disability not due to SCI. A detailed description of the full sample, intervention and longitudinal outcomes from baseline-seven month follow-up can be found elsewhere.¹²

Measures

The measures from the *Well on Wheels* intervention were the primary focus, as group-level results from Zemper et al.¹² reported no significant differences between intervention and control groups. We suspected response heterogeneity may play a role in the lack of group-level differences in outcomes and utilized the following SCT-based outcome measures that were the target of the intervention to define “responders” and “non-responders.” We then used demographic and injury characteristic measures to provide novel information regarding response heterogeneity and inform future wellness interventions for individuals with SCI.

Demographics and injury characteristics—Participants self-reported their age, gender, race, education, employment, and marital status. Years post-injury was calculated by subtracting participants’ age at baseline from age at injury. Participants reported level of injury as paraplegia or tetraplegia, and this was verified by a physician reported AIS classification.

Outcome Variables—The 5-item Satisfaction with Life Scale (SWLS) was used to measure global cognitive judgments of satisfaction with one’s life.¹³ Healthy lifestyle self-efficacy or self-perceived ability to implement health-promoting behaviors were assessed using the 28-item Self-rated Abilities for Health Practice Scale (SAHP).¹⁴ The 52-item

Health-Promoting Lifestyle Profile II (HPLP) was used to assess personal health-promoting habits.¹⁵ The Secondary Conditions Scale (SCS) was used to report new problems related to SCI.¹⁶ The SCS was modified from reporting secondary conditions experienced over a year to a 3-month period in order to be appropriate for the data collection intervals. The 10-item Perceived Stress Scale (PSS) measures the degree to which situations in one's life are appraised as stressful.¹⁷

Statistical Analysis

Descriptive statistics of the mean control group change scores on outcome variables were utilized to classify response groups (i.e., treatment response heterogeneity). Mean control group change scores at 3 months were used to classify intervention participants as responders or non-responders. Specifically, positive changes higher than the mean control group change at 3 months on each outcome was considered positive response because intervention participants are theoretically reporting a differential outcome compared to no intervention. Intervention participants were then split into groups based on the number of outcome variables on which they score higher than the control mean. Non-responder was defined as negative or no change in 3 out of 5 variables of interest (i.e. lower for SWLS, SAHP, and HPLP or higher for SCS and PSS). Baseline differences between responders and non-responders were examined using t-tests and chi-squared analyses.

The Classification and Regression Tree (CART) method was used to split data into segments that are as homogenous as possible with respect to response group status. Demographic and injury characteristics were entered as predictor variables until terminal nodes were identified. Gini Index was used to help avoid overfitting, which splits the nodes into two groups as homogenous as possible with respect to the child nodes. Criteria were determined for minimum cases per node; minimum cases in a parent node of 30% (n = 9) and in a child node 15% (n = 4). Results of 10-fold cross-validation were evaluated to avoid overfitting.

RESULTS

Descriptive

Table 1 provides sociodemographic and injury characteristics of the 29 intervention group participants who completed baseline and 3-month assessment. The mean age at baseline was 43.2 ± 11.2 years and years post-injury was 12.0 ± 9.8 . Most participants were male (n=19;65%), identified as having paraplegia (n=16;55%), and had complete injuries (n=18;62%). There were no significant differences in demographic variables between responders versus non-responders at baseline. However, responders reported significantly greater secondary condition severity ($P=0.03$) and fewer health-promoting behaviors ($P=0.02$).

Treatment Response Heterogeneity

Eighteen intervention participants were classified as responders and 11 were classified as non-responders after the 3-month intensive intervention phase. Figure 1 shows the results of the CART decision tree with 3 terminal nodes predicting response group. Participants who were non-responders to the intervention were more likely to be single/divorced than married

(52% versus 17%). Among those who were single/divorced, participants who were 50 years old were most likely to be non-responders (62% versus 25%). Calculated risk estimates for the tree were 0.28 ± 0.08 , indicating that the response group predicted by the tree was incorrect for 28% of the cases. Overall, based on sociodemographic and injury characteristics, this decision tree model predicted 72.7% of non-responders and 72.2% of responders. Further information on each participants' outcome response and control group mean differences are included in Supplemental Table 1.

DISCUSSION

The purpose of this study was to explore non-modifiable variables associated with response to a wellness intervention for persons with SCI. Participants who were non-responders to the intervention were more likely to be single or divorced and 50 years old. Our findings provide useful information for determining who is most likely to not respond to the strategies and curriculum used in *Well on Wheels*. The procedures used in this study are an example of how response heterogeneity can be examined in behavioral interventions.

The outcome variables of interest in the *Well on Wheels* study aligned with Stuijbergen's model of QOL in individuals with chronic disabling conditions¹¹ and SCT behavior change mechanisms.¹⁰ Participants who were married were most likely to demonstrate improvement in outcomes following 3-month intervention. SCT posits that environmental variables, including social support, have a significant influence on health-promoting behaviors. For example, Anderson, Winett, and Wojcik¹⁸ found that social support was positively correlated with engagement in healthier nutrition behaviors. We believe the association between social support and behavior change may account for differences in *Well on Wheels* intervention response because partners may provide tangible support (e.g., help with medical needs and activities of daily living) and emotional support. Partners can help facilitate the adjustment process as long as marital satisfaction is also high; strain in marital relationships is associated with negative outcomes following SCI.¹⁹

Although our findings suggest marital status may provide social support, marital status is not modifiable using a behavioral intervention. For individuals who are single/divorced, peers may provide tangible and/or emotional social support. This study did not measure perceptions of peer support, but we posit that perceptions of peer support are a potential avenue for future research, particularly among persons who do not have established social support. Indeed, peer support is a great resource currently utilized by many rehabilitation hospitals that may help individuals adjust from intensive rehabilitation to community-living. It is relatively common to include social support in wellness interventions for patients with SCI.^{5,20} For example, a family-based intervention targeting social support reported promising results, increasing wellbeing in both individuals with SCI and caregivers.²¹ Interventions with more individualized components focused on medical management of SCI show improvements in self-management of secondary health conditions and reducing costs; however, based on our results, we posit that social support may partially mediate adjustment and behavior change that should be established prior to individualized interventions.^{6,19} Further research is needed to better understand the driving aspects of support that having a spouse or partner provides; we posit that all individuals with SCI can benefit from tangible

and/or emotional support that contributes to self-management. Therefore, healthcare providers should consider marital status and opportunities for support that may be present for individuals they see in practice.

Additionally, our results revealed that participants who were less than 50 years old were more likely to be non-responders. This association could have been confounded by other variables such as years post-injury or the large age range in this small sample (20–80 years). However, it is also important to consider that individuals who were responders to the intervention started with more secondary conditions and fewer health-promoting behaviors. Individuals who begin with more secondary conditions and fewer health-promoting behaviors may be more motivated to change. Motivation has been identified as a partial mediator of self-efficacy and health behavior change that may be vital in identifying individuals most likely to respond to interventions.²² This finding is striking as more secondary conditions are associated with older age, whereas older individuals may engage in more health-promoting behaviors.^{15,23} Therefore, we would expect younger individuals to benefit more from the intervention, but older individuals were more likely to respond if they were single/divorced. It is possible that older individuals who are single/divorced had established social support in their lives that aided in positive behavior change. These associations should be further examined to better understand the relationship between age and response to SCT-based interventions.

Limitations in this study include the lack of statistical power from a smaller sample size. Specifically in this analysis, the small sample provided instability in the decision tree. The investigators choose the tree that best fit the data without overfitting. Further, the smaller sample size prevents capability to adequately control for major confounding variables such as age and disability status. More research is needed to investigate if demographics and injury factors can be used to identify individuals who do not respond to interventions and the best metrics to use in defining treatment response. Given differences between response groups at baseline we investigated whether baseline levels of health-promoting behaviors were a primary determinant of response status in this study. We have included Supplemental Table 1, which highlights each participant's profile of change and provides transparency to address that concern. Lastly, this study does not include qualitative inquiry regarding participant perceptions and experiences following the intervention that would be valuable in future studies.

This study identified the differential effects of the *Well on Wheels* intervention, addressing treatment response heterogeneity in behavioral interventions. Precision health is a recent push in medicine and public health to provide each patient with a treatment appropriate to their needs; this approach challenges the status quo that programs are not one-size-fits-all.²⁴ The goal of intervention research is to identify programs that are effective in making a lasting positive impact on patients. More specifically, in the rehabilitation realm, the goal is to improve self-efficacy and independence so that individuals can take skills with them to enhance their QOL and self-management. We posit that there needs to be a shift in the field to spend more time and resources to understand not only which interventions are effective, but also who these programs benefit most and who may require altered intervention strategies. Investigators may want to consider novel research designs in addressing response

heterogeneity such as Sequential Multiple Assignment Randomized Trial (SMART) interventions.²⁵ SMART interventions focus on identifying non-response at specific decision points in an intervention protocol and altering strategies to maximize participant uptake and costs. Our findings suggest that *Well on Wheels* did not benefit most individuals who were not married and younger. Therefore, future interventions could be adapted with resources and support specific to the current needs of individuals with SCI who are not married and young or integrate SMART research designs that dynamically modify protocols in relation to response.

Conclusions

Our findings highlight that marital status may be an important non-modifiable factor to consider when creating behavioral interventions for persons with SCI. Specifically, single/divorced individuals may respond differently to interventions as well as younger persons with SCI. Future studies with larger sample sizes are warranted in order to identify non-modifiable characteristics associated with intervention response can aid health care practitioners in expeditiously screening patients and referring them for services. Such characteristics may also help guide the creation and modification of interventions to address individual needs, in line with a precision medicine approach.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Funding: Funding was provided by the University of Michigan Health Systems (UHMS) Venture Investment Fund; the UHMS General Clinical Research Center [NIH grant number M01-RR00042]; and the University of Michigan Spinal Cord Injury Model System Program, funded by NIDLRR [grant number H133N000009].

All procedures were approved by University of Michigan's Institutional Review Board. Informed consent was obtained from all participants prior to data collection. Authors have no competing interests pertaining to the research.

REFERENCES

1. Stuifbergen AK, Morris M, Jung JH, Pierini D, Morgan S. Benefits of wellness interventions for persons with chronic and disabling conditions: A review of the evidence. *Disabil Health J*. 2010;3(3):133–145. [PubMed: 20628583]
2. Davidson KW, Peacock J, Kronish IM, Edmondson D. Personalizing behavioral interventions through single-patient (N-of-1) trials. *Soc Personal Psychol Compass*. 2014;8(8):408–421. [PubMed: 25267928]
3. Wilmore J, Leon AS, Rao D, Skinner J, Gagnon J, Bouchard C. Genetics, response to exercise, and risk factors: The HERITAGE Family Study. *World Rev Nutr Diet*. 1997;81:72–83. [PubMed: 9287505]
4. Motl RW, Dlugonski D, Pilutti LA, Klaren RE. Does the effect of a physical activity behavioral intervention vary by characteristics of people with multiple sclerosis? *Int J MS Care*. 2015;17(2): 65–72. [PubMed: 25892976]
5. Block P, Vanner EA, Keys CB, Rimmer JH, Skeels SE. Project Shake-It-Up: Using health promotion, capacity building and a disability studies framework to increase self efficacy. *Disabil Rehabil*. 2010;32(9):741–754. [PubMed: 20302442]

6. Dicianno BE, Lovelace J, Peele P, et al. Effectiveness of a wellness program for individuals with spina bifida and spinal cord injury within an integrated delivery system. *Arch Phys Med Rehabil*. 2016;97(11):1969–1978. [PubMed: 27311718]
7. Morrison JD, Stuifbergen AK. Outcome expectations and physical activity in persons with longstanding multiple sclerosis. *J Neurosci Nurs*. 2014;46(3):171–179. [PubMed: 24670432]
8. Phillips VL, Vesmarovich S, Hauber R, Wiggers E, Egner A. Telehealth: Reaching out to newly injured spinal cord patients. *Public Health Rep*. 2001;116 Suppl 1:94–102. [PubMed: 11889278]
9. Verwer JH, van Leeuwen CM, Bolier L, Post MW. Feasibility of an online well-being intervention for people with spinal cord injury: A pilot study. *Spinal cord*. 2016;54(6):473–477. [PubMed: 26481702]
10. Bandura A Health promotion by social cognitive means. *Health Educ Behav*. 2004;31(2):143–164. [PubMed: 15090118]
11. Stuifbergen AK, Becker HA. Predictors of health-promoting lifestyles in persons with disabilities. *Res Nurs Health*. 1994;17(1):3–13. [PubMed: 8134609]
12. Zemper ED, Tate DG, Roller S, et al. Assessment of a holistic wellness program for persons with spinal cord injury. *Am J Phys Med Rehabil*. 2003;82(12):957–968; quiz 969–971. [PubMed: 14627933]
13. Diener E, Emmons RA, Larsen RJ, Griffin S. The satisfaction with life scale. *J Pers Assess*. 1985;49(1):71–75. [PubMed: 16367493]
14. Becker H, Stuifbergen A, Oh HS, Hall S. Self-rated abilities for health practices: A health self-efficacy measure. *Am J Health Behav*. 1993.
15. Walker SN, Volkan K, Sechrist KR, Pender NJ. Health-promoting life styles of older adults: Comparisons with young and middle-aged adults, correlates and patterns. *ANS Adv Nurs Sci*. 1988;11(1):76–90. [PubMed: 3140723]
16. Seekins T, Smith N, McCleary T, Clay J, Walsh J. Secondary disability prevention: Involving consumers in the development of a public health surveillance instrument. *J Disabil Policy Stud*. 1990;1(3):21–36.
17. Cohen S, Kamarck T, Mermelstein R. Perceived stress scale. *Measuring stress: A guide for health and social scientists*. 1994:235–283.
18. Anderson ES, Winett RA, Wojcik JR. Self-regulation, self-efficacy, outcome expectations, and social support: Social cognitive theory and nutrition behavior. *Ann Behav Med*. 2007;34(3):304–312. [PubMed: 18020940]
19. Muller R, Gertz KJ, Molton IR, et al. Effects of a tailored positive psychology intervention on well-being and pain in individuals with chronic pain and a physical disability: A feasibility trial. *Clin J Pain*. 2016;32(1):32–44. [PubMed: 25724020]
20. Ljungberg I, Kroll T, Libin A, Gordon S. Using peer mentoring for people with spinal cord injury to enhance self-efficacy beliefs and prevent medical complications. *J Clin Nurs*. 2011;20(3-4):351–358. [PubMed: 21219518]
21. Rodgers ML, Strode AD, Norell DM, Short RA, Dyck DG, Becker B. Adapting multiple-family group treatment for brain and spinal cord injury intervention development and preliminary outcomes. *Am J Phys Med Rehabil*. 2007;86(6):482–492. [PubMed: 17515688]
22. Kelly RB, Zyzanski SJ, Alemagno SA. Prediction of motivation and behavior change following health promotion: Role of health beliefs, social support, and self-efficacy. *Soc Sci Med*. 1991;32(3):311–320. [PubMed: 2024141]
23. Charlifue SW, Weitzenkamp DA, Whiteneck GG. Longitudinal outcomes in spinal cord injury: Aging, secondary conditions, and well-being. *Arch Phys Med Rehabil*. 1999;80(11):1429–1434. [PubMed: 10569437]
24. Khoury MJ, Iademarco MF, Riley WT. Precision public health for the era of precision medicine. *Am J Prev Med*. 2016;50(3):398–401. [PubMed: 26547538]
25. Collins LM, Murphy SA, Strecher V. The multiphase optimization strategy (MOST) and the sequential multiple assignment randomized trial (SMART): new methods for more potent eHealth interventions. *Am J Prev Med*. 2007; 5 1:32(5):S112–8. [PubMed: 17466815]

Figure 1. CART Decision Tree Predicting Response to the Well on Wheels Intervention

Figure displaying results of decision tree regression analysis predicting treatment response in Well on Wheels Intervention.

Table 1.

Baseline sociodemographic and injury characteristics of Well on Wheels Intervention Group, & Response vs. Non-Response Intervention Groups

	Intervention N=29	Responders N=18	Non-Responders N=11
	n(%) or Mean±SD	n(%) or Mean±SD	n(%) or Mean±SD
Age at enrollment (years)	43.2±11.2	44.8±11.4	40.6±11.1
Years since injury	12.0±9.8	11.5±10.1	12.9±9.6
Sex			
Female	10 (34.5)	7 (70.0)	3 (30.0)
Male	19 (65.5)	11(61.1)	8 (72.7)
Level of Injury [†]			
Paraplegia	16 (55.2)	10 (62.5)	6 (37.5)
Tetraplegia	13 (44.8)	8 (61.5)	5 (38.5)
AIS Completeness [†]			
Complete (A)	18 (62.1)	11 (61.1)	7 (38.9)
Incomplete (B-D)	11 (37.9)	7 (63.6)	4 (36.4)
Race			
White	25 (86.2)	16 (64.0)	9 (36.0)
Not White	4 (13.8)	2 (50.0)	2 (50.0)
Education [†]			
High School	5 (17.2)	3 (60.0)	2 (40.0)
Some College	11 (37.9)	6 (54.5)	5 (45.5)
College Degree or More	13 (44.8)	9 (69.2)	4 (30.8)
Employment			
Unemployed	16 (55.2)	10 (62.5)	6 (37.5)
Employed	9 (31.0)	6 (66.7)	3 (33.3)
Retired	4 (13.8)	2 (50.0)	2 (50.0)
Marital Status			
Single	10 (34.5)	4 (40.0)	6 (60.0)
Married	12 (41.4)	10 (83.3)	2 (16.7)
Divorced	7 (24.1)	4 (57.1)	3 (42.9)
Primary Outcomes			
SWLS	19.9±7.3	19.3±7.4	20.8±7.3
SAHP	90.1±18.0	86.3±18.2	96.4±16.7
SCS Severity	23.9±15.7	28.7±16.1 [*]	16.1±11.8 [*]

	Intervention N=29	Responders N=18	Non-Responders N=11
	n(%) or Mean±SD	n(%) or Mean±SD	n(%) or Mean±SD
HPLP	130.4±24.6	122.4±17.2 *	143.5±29.8 *
PSS	30.0±4.7	33.8±4.7	31.7±4.4

AIS- American Spinal Cord Injury Association impairment scale, SWLS- Satisfaction with life scale, SAHP- Self-rated abilities for health practices scale, SCS Severity- Secondary condition scale severity, HPLP- Health-promoting lifestyle profile, PSS- Perceived stress scale

* = Significant differences $P < 0.05$

[†]Missing Baseline Values: Level of injury=2, AIS=2, Education=1