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Cross-cultural Adaptation and Implementation of Good Life with Osteoarthritis in Denmark (GLA:D™): group education and exercise for hip and knee osteoarthritis is feasible in Canada

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Running Title: Testing an Adapted Hip/Knee OA Program
Abstract (248 words)

Objective: Adapt and evaluate the feasibility of implementing Good Life with osteoArthritis in Denmark (GLA:D™) in Canada for people with mild to severe hip/knee osteoarthritis.

Methods: Patients triaged to non-surgical management participated in two education sessions and 12 supervised, neuromuscular exercise classes. We used the RE-AIM implementation framework evaluating outcomes of Reach, Effectiveness/Efficacy, Adoption, Implementation and Maintenance. Patients completed surveys pre-program and at 3 months follow-up. Program fidelity was evaluated at 4 observations against a priori criteria. We conducted semi-structured interviews with therapists post-program.

Results: 72 patients consented to participate, 59 started the program and one withdrew on physician advice. The remaining 58 provided follow-up data. Mean age was 67 years; 78% were female and 52% had BMI >25. The effect of the program was demonstrated: 40% improvement in pain with 59% achieving a clinically important improvement of ≥2 points on the Numeric Pain Rating scale. Statistically significant improvement also occurred in the Hip disability/Knee injury and Osteoarthritis Outcome Score subscales. 24% reported increased physical activity. Program fidelity was demonstrated with all criteria met. Therapists emphasized that rolling recruitment allowed appropriate supervision and resulted in participants encouraging each other. 99% of participants indicated they benefitted from and were satisfied with the program and 90% reported using the knowledge daily. 52% were willing to pay >$250 Cdn for the program.

Conclusion: GLA:D™ implementation was feasible in the Canadian context with results similar to those of >7,000 participants in Denmark. Implementation and evaluation of GLA:D™ Canada is now occurring nationally.
Introduction

Guidelines support education, exercise and weight management as first-line non-operative interventions for hip and knee osteoarthritis (OA)\(^1\) but the literature shows that first-line management often is not offered to patients\(^4\)\(^6\). Work by Bone and Joint Canada identified a paucity of programs for people requiring non-surgical management for hip and knee OA and the need for feasible, evidence-based care in Canada\(^9\).

Some programs have been developed to address this care gap\(^10\). Good Life with osteoArthritis in Denmark (GLA:D\(^\text{TM}\)) is one program that has documented feasibility and effectiveness\(^11\)\(^-\)\(^18\). GLA:D\(^\text{TM}\), described in detail elsewhere\(^11\), includes a 2-day therapist training program, patient education and 6 weeks, twice a week, of supervised, individualized neuromuscular (NM) exercise in a group setting\(^19\) for people with mild to severe hip and knee OA symptoms delivered by trained physiotherapists (PTs) in Denmark.\(^11\) Patient outcomes are collected in a national registry at baseline and 3 and 12 months follow-up.

Over two years, the GLA:D\(^\text{TM}\) program was offered at 286 sites in Denmark with >7000 participating in the program and providing outcome data\(^11\). Based on the registry data, participants had significant improvements in pain intensity at 3 and 12 months. Additionally, quality of life scores and the 30-second chair stand and the 40-meter walk tests improved. People were more likely to be physically active at 3 months. Fewer participants took pain killers following the program and the proportion on sick leave at 12 month follow-up decreased.

Although the implementation of GLA:D\(^\text{TM}\) was successful in Denmark\(^11\), the health care context and management of hip and knee OA is unique to Canada. We, therefore, evaluated the feasibility of implementing GLA:D\(^\text{TM}\) in Canada. The objectives were to: 1) cross-culturally adapt
the GLA:D™ therapist training and patient education materials for the Canadian context; and,

2) evaluate implementation outcomes.

**Methods**

**Cross-cultural Adaptation of Materials**

The first step to enable implementation and evaluation included cross-cultural adaptation of the GLA:D™ program materials. The therapist training and patient education materials were translated from Danish to English by a native Danish speaker fluent in English. Program developers (ER and STS), fluent in both Danish and English, reviewed the materials to ensure the translation represented the intended meaning. These translated materials were then reviewed independently by members of the Canadian team (AMD, RW and DK) for clarity and comprehension, consulting with the developers of GLA:D™ to ensure proposed revisions conveyed the original meaning. Opportunities to add supporting epidemiologic data and research evidence from Canada to the therapist training materials were identified.

**Implementation and Evaluation Study**

**Study Design**

The implementation feasibility study was conducted from March to November 2016. Our study was grounded in the RE-AIM implementation framework. The operationalization of the framework components, Reach, Effectiveness/Efficacy, Adoption, Implementation and Maintenance, are described in Table 1. We used a mixed methods design; a pre-post design with 3 month follow-up to evaluate Reach, Effectiveness and Maintenance and direct
observation of classes and semi-structured interviews with the therapists delivering the program to evaluate implementation.

**Participants**

Three physiotherapists who attended the first GLA:D™ course given by the developers in Canada delivered the program.

GLA:D™ Canada program participants were recruited from the Hip and Knee Arthritis Program at the Sunnybrook Holland Orthopaedic & Arthritic Centre, Toronto, Canada. Patients referred for consideration of total hip or knee replacement (TJR) were assessed by an Advanced Practice Physiotherapist who identified potential participants who were not surgical candidates. Interested participants were screened for eligibility by the research assistant. Eligibility criteria included: hip or knee OA requiring non-surgical management; age 30 years or older; English fluency; and, consent to participate. Participants also had to agree to travel to the Centre to attend the program. Exclusion criteria included: prior or booked for TJR on the designated knee or hip; acute injury in the past six months; inability to follow instructions/consent; and, a health condition precluding exercise. Individuals completed the validated Physical Activity Readiness Questionnaire (PAR-Q+)\(^{21,22}\); those who failed the screening required clearance from their physician to participate in the program.

**GLA:D™ Canada Intervention**

The intervention included 2 patient education sessions and a supervised NM exercise program twice a week for six weeks. The aim of the education was to encourage the patients to actively engage in the management of their hip and knee OA. The two 60-minute educational sessions were delivered in a class setting by one of the therapists providing the exercise classes. The first
session focused on diagnosis, the etiology, symptoms and risk factors of hip and knee OA. Treatment options were introduced, including discussion of exercising with pain and how to monitor pain. The second session provided an in depth discussion of treatment, with the main focus on the beneficial effects of exercise on OA symptoms and increasing physical activity, as well as guidance in self-help tools. The physiotherapist facilitated discussion and interaction among the patients during both sessions.

The purpose of the NM training program is to improve sensorimotor control of the lower limb. Participants completed 6 weeks, twice a week of supervised, targeted and individualized exercise in a group setting as described by Ageberg et al.14. During the course of the exercise classes, home exercises were encouraged as individuals developed quality movement and participants were encouraged to increase their engagement in enjoyable physical activities.

Data Collection

Electronic surveys were completed by participants pre-program and at 3 months follow-up that included descriptive data and patient-reported outcomes (described below). Descriptive data included age, sex, marital status, education level, self-reported height and weight to calculate body mass index (BMI) and most affected knee or hip.

Therapists recorded the 30-second chair stand and 40-meter walk test scores pre-program and at the start of the last exercise class.
An individual familiar with but not involved in providing the program (AMD) conducted 4 direct observations over the course of the study to evaluate treatment fidelity and clinical processes based on a priori criteria (described below).

After all participants completed the program, semi-structured interviews were conducted with the therapists to understand process adaptation and facilitators and challenges to program delivery.

**Implementation Outcomes**

Implementation feasibility focused on outcomes for Reach (within the context of our implementation at a single site), individual effects of the program, and Implementation (fidelity and clinical processes) and individual-level Maintenance. Adoption was not evaluated in this single site study.

**Reach**

We tracked the number screened during the study period and report the absolute number and proportion of those who participated in the program.

**Program Effect/Efficacy**

Adverse events were recorded by the therapist. These included any concerns or issues raised by the participant including symptoms beyond muscle soreness from exercising, injury or psychological issues, new illnesses etc.

Our primary outcome was pain intensity measured by the reliable and valid Numeric Pain Rating Scale (NPRS). It is scored from 0-10 with 0 indicating no pain and the minimal clinically important difference is 2 points.$^{23}$
We included several secondary outcomes. The Hip disability and Osteoarthritis Outcome Score (HOOS) and Knee injury and Osteoarthritis Outcome Score (KOOS) subscales are scored 0-100 with higher scores representing less symptoms and better function and quality of life (QOL)\(^{24-26}\). Functional tests included the 30-second chair stand and the 40-meter walk test\(^{27}\). Participants self-reported physical activity based on the number of days in a typical week with at least 30 minutes of moderate intensity physical activity\(^{28}\).

Confidence in managing OA was evaluated with the 8-item Arthritis Self-Efficacy Scale\(^{29}\). It is scored 1-10 with higher scores indicating greater self-efficacy.

Medications were reported as no/yes responses to type of medication (e.g. narcotics, non-steroidal anti-inflammatory drugs (NSAIDS), topical NSAID, neuropathic pain medication, alternative therapies) at baseline and 3 months.

Participants reported perceived benefit and satisfaction with participation in the GLA:D\(^{TM}\) Canada program on a 4-point scale ranging from not at all to very beneficial and not at all to very satisfied respectively at follow-up.

**Implementation**

Evaluation of program fidelity, guided by the framework of Carroll\(^{30}\), was monitored by: 1) participant attendance at the education and exercise sessions as recorded by the therapist; and, 2) 4 direct observations using a standardized checklist\(^{31}\). The observations were conducted by the principle investigator (AD), who is trained in the program and familiar with NM. The therapist was aware the class would be observed and the participants were informed that a visitor would be moving about the class observing people performing the exercises and taking notes. Therapist factors (i.e., direct and clear participant instructions, appropriate supervision,
purposeful interaction with participant to correct lower limb alignment, appropriate exercise progression and provision of physical activity guidance, allotted time per session), participant factors (i.e., demonstration of understanding of instructions, acceptance of feedback by therapist, and engagement in exercises) and external factors (i.e., adequacy of space, number of participants) were evaluated as ‘not met, partially met, completely met’. While not solicited, spontaneous comments by participants and therapists were recorded verbatim as indicators of engagement and the observer engaged in limited conversation with the participants only if they initiated the conversation.

One-on-one semi-structured interviews were conducted with the therapists to understand facilitators and challenges to program delivery. The interviews were conducted by a physiotherapist and clinical epidemiologist (AMD) who has led and participated in several qualitative studies. The therapists and interviewer became acquainted with each other in the context of this study. The interview guide (Appendix 1) included topics related to experiences providing the program, prior information that would have helped in program delivery and advice for other therapists and management about program delivery. Interviews which ranged from 30 to 47 minutes were recorded and transcribed verbatim.

**Maintenance**

Participant adherence to treatment was recorded on a 5-point scale (never, every month, every week, every day, several times a day).

Finally, we asked participants, given their experience, how much they would be willing to pay to participate in the GLA:D™ Canada program ranging from 100 to 301 or more Canadian dollars in 50 dollar increments.
Analysis

Separate analyses were conducted for the hip and knee participants using SAS v9.3. Frequencies and proportions for categorical variables and means and standard deviations (sd) or medians and interquartile ranges for continuous variables were calculated after checking normality assumptions. Outcomes were evaluated by change scores (pre-program to 3 month follow-up) with 95% confidence intervals with the exception that the Wilcoxon test was used for the count data from the 30 second chair stand test. Missing item responses for patient-reported outcomes were imputed according to the developer instructions.

Interview data were analyzed thematically using content analysis by the interviewer. After multiple readings, codes were generated from meaning units of the text. The codes were then grouped into themes. To achieve research rigor, memoing occurred after each interview. Given the interviewer’s training as a PT, her knowledge of the intervention and role as the primary investigator of the study, she also documented pre-existing ideas and perspectives in an attempt to identify any biases. Care was taken to consider how these may have influenced the interpretation of the data.

Sample Size

With change in pain as our primary outcome, based on Danish pilot data with a mean change of -12.7, sd of the mean 19.8 on a 0-100 pain visual analogue scale, 28 participants were required to detect this difference with alpha=0.05 and 90% power. To ensure a sufficiently large sample to inform future implementation, our goal was to recruit 70 participants (approximately 35 each with hip and knee OA) anticipating 10 participants would be lost to follow-up.
This study was approved by the institutional research ethics review board and was registered at ClinicalTrials.gov (NCT02693873).

Results

Adaptation of GLA:D™ Materials

The translated version of the patient and therapist training materials were revised to Canadian English terminology (e.g. paracetamol was revised to acetaminophen, etc.). Epidemiologic data on the burden of OA, and gaps in non-surgical and surgical care (e.g. total joint replacement and arthroscopy rates) were added to contextualize the therapist training materials to Canada. The translated patient education materials were revised to the grade 6 language level that is recommended for patient resources in Canada\textsuperscript{34,35}.

Implementation Outcomes

Reach

Seventy-two people were eligible and consented to participate during the 6 month recruitment period. Thirteen never enrolled in the GLA:D™Canada program for various reasons (Figure 1). Fifty-nine participants enrolled in the program with 58 completing the program.

Table 2 provides the baseline characteristics of the 22 and 36 participants with hip and knee OA respectively who completed the program. On average, participants were in their 60s (range 47 to 90 years) and most were overweight or obese. Baseline NPRS scores ranged from 1 to 7 for the hip participants and from 1 to 10 for the knee participants.

Program Effect/Efficacy Outcomes
One of the 59 who started the program experienced an adverse event, increased
generalized pain, and discontinued on the advice of their rheumatologist. Fifty-eight
participants completed the three-month follow-up.

There was significant improvement in the NPRS for both hip and knee participants
(Table 3). Pain decreased 40% on average. Twelve of 22 (55%) hip participants and 22 of 36
(61%) knee participants had a clinically important improvement.

HOOS and KOOS subscales demonstrated improvement with mean change ranging from
5.4 to 12.0 points (Table 3). Participants with hip OA on average completed 4.1 additional chair
stands in 30 seconds and decreased the time required to walk 40 meters by 4.5 seconds
(average increased walking speed 0.3 m/s) whereas the knee participants improved by 2.7 chair
stands with a decreased 40 meter walk time of 5.0 seconds (average increased walking speed
0.2 m/s).

Overall, 23.6% self-reported increased physical activity at 3 months, 22.7% (95% CI:
0.10, 0.43) of hip participants and 24.2% (95% CI: 0.13, 0.41) of knee participants.

Self-efficacy in managing OA showed small significant, although likely not meaningful,
change for those with hip OA.

There was little change in the participants’ use of medication. Four hip participants
reported using no medication prior to and following the program and 11 knee participants
indicated that they used no medication at the end of the program compared to 9 at baseline. Of
those using medication, the majority in both groups reported using acetaminophen or non-
steroidal anti-inflammatory medication (NSAID) (10 hip and 14 knee participants). Thirty-six
percent of knee patients (n=13) reported using topical NSAID cream whereas 23% of hip
patients (n=5) used the cream. Narcotics or neuropathic pain medications were used by 3 participants.

Ninety-nine percent with hip and with knee OA reported that the program was beneficial with 75% (n=44) indicating ‘very beneficial’. Ninety-nine and 90% of people with hip and knee OA respectively were very satisfied with the program.

Implementation

Program Fidelity

All participants attended both education sessions. Twenty and 35 hip and knee participants respectively (95%) attended all 12 exercise sessions while 3 attended 8 sessions (2 hip participants and 1 knee participant) and 100% provided outcome data.

Class observations were conducted towards the end of months 1, 2, 6 and 8 of the full study period. There were 6 participants (mixed men and women) in each class except for the last observation when the final 3 study participants were finishing their exercises sessions. As rolling recruitment was used, participants in a given class had attended different numbers of exercise classes (e.g. some on session 3 or 4, while others were on session 8 or 9).

At all observations, there was fidelity of the intervention based on the therapist, participant and external a priori criteria (Table 4). Observation confirmed that the therapist moved amongst the participants, correcting alignment verbally and through tactile input as necessary; exercises were progressed for some participants during the class. During the first observation, participants asked for guidance moving through the stations and for reminders of the exercises to be performed. At the subsequent observation, it was noted that pictures and brief descriptions of each exercise station had been posted on the wall for participant
reference. The participants through this and the remaining observations routinely used these guides to move themselves independently through the exercise stations. Space was appropriately prepared and classes started and finished on time.

Participants demonstrated their understanding of quality performance of the exercises, e.g. a male participant, preparing for the sitting hamstring strengthening exercise, corrected the chair position for proper alignment without cueing and a female participant performing hip slides for the stability exercise, automatically corrected her alignment. Quiet ‘self-chat’ was used by a number of participants: ‘that one wasn’t right; I need to do it again; [participant resets themselves] that one was good’ (female); performing the step box functional exercise: ‘sit [i.e. a partial squat] and step, sit and step’ (male). Additionally, participants spontaneously asked the therapist to progress their exercises: ‘I did the green [exercise band] with the other one [leg] but I think I can do the harder one [exercise band] on this leg.’ (male)

**Therapist interviews**

Each of the therapists delivering the program had more than 10 years’ experience in orthopedic rehabilitation.

All were enthusiastic about the program and described the results: ‘It works! I saw the changes...the smiles on the faces.’ (PT1) One therapist described the program as giving participants ‘permission’ to be active knowing they could manage their symptoms; it was ‘empowering’. (PT3)

The therapists also described aspects of the program and its delivery specific to implementation which formed a core theme of ‘therapist learnings’. Within this core theme, they talked about operational issues related to the organization of and delivery of the program
that were distinct from the learnings described working with the program participants. These two subthemes were identified as ‘Operational Processes’ and ‘Working with Course Participants during the Classes’.

**Operational Processes**

Three therapists allowed scheduling of the classes at different times and days of the week, providing flexibility for participant schedules and coverage by another therapist. The education sessions were offered once a week alternating between session 1 and 2. New participant assessments and final testing were scheduled 30 minutes before a supervised exercise class as needed. Participants chose a scheduled preferred exercise time, although they were allowed to attend at an ‘off schedule’ time if needed (e.g. an out of town work trip). As recruitment increased with concomitant demands for exercise classes, classes were offered 6 times per week, twice early morning and 4 times late afternoon. This allowed some control of class size.

All therapists talked about the importance of class size and managing new participants. They indicated that the class required ‘intense supervision’. (PT 1, 2, 3) They described the difficulties in the first program sessions when most participants were new and required more guidance and correction of proper form. They advised that initial classes needed to be small (3 or 4) people with rolling recruitment very beneficial so that they were able to institute a one graduate, one new participant process with increasing class size to 8 participants. Therapists indicated that more than 1 or 2 new participants in a class were difficult to effectively manage while providing supervision for the entire class. (PT1, PT2) Participants were described as becoming more independent and requiring less supervision after about 6 exercise sessions.
Therapists also described how more senior participants encouraged and supported newer participants. One therapist described the challenges of supervision when space did not allow clear line of sight. (PT1)

**Working with Course Participants during the Classes**

All therapists agreed that the first education session was critical to reducing the participant’s anxiety related to exercising when their main complaint was pain with activity. If a participant could not attend the first education class prior to starting the exercises, the therapist spent time during the class discussing the interaction of pain and exercise, how exercise improved symptoms and how to monitor pain. Additionally, they described ‘reinforcing information about exercising with pain’ (PT1) and the ‘importance of pain monitoring’ (PT3) throughout the exercise classes.

Two of the therapists also described the importance of empowering the patients rather than ‘pushing’ them. (PT1, PT2) This was achieved was by ‘giving choices’; e.g. indicating that the participant could ‘do this exercise or this [alternate] exercise’. (PT1) The therapists also described how exercise progression was most effective when the participant requested progression.

**Maintenance**

Ongoing adherence to the education and exercises was reported with 91% (20/22) hip and 89% (32/36) knee participants indicating use of the information on a daily basis at follow-up.
Forty-five (of 58) responded to the willingness to pay question. Fifty-two percent reported that they would be willing to pay $251 or more to attend the GLA:D™ Canada program and the remainder indicated they would pay $100-250.

Discussion

This study demonstrated that an evidenced-based education and neuromuscular exercise program, GLA:D™ developed and implemented in Denmark, could be adapted and feasibly implemented in the Canadian context based on outcomes reflecting the RE-AIM framework components, Reach, Effectiveness, Implementation and Maintenance. Achievement of both individual and institutional level outcomes was critical as feasibility and, ultimately program implementation success, need to be considered in the context of benefits for patients and institutional implementation processes. Understanding the impact and issues related to program implementation are required to support spread to the real world setting to ultimately achieve impact at a larger population level.

We achieved Reach in the context of this single site feasibility study. Our rate of recruitment to the study was about 10-12 per month and a large proportion (58/72, 82%) completed the program. As noted in Figure 1, 13 did not start the program for a variety of different reasons. Of those starting the program (n=59) our retention was very high (n=58). Given the need to travel to the site, these data suggest that there are sufficient numbers of people attending this Center who can access the program. However, this site is a center of excellence for TJR where patients are most frequently referred by primary care physicians for consideration of joint replacement. Hence, our evaluation of Reach can only be interpreted in
this context. While these people were deemed non-surgical candidates, it is also recognized that the majority of people with hip and knee OA are not referred for specialist care\textsuperscript{36}.

The characteristics of our sample are similar to those who attended the GLA:D\textsuperscript{TM} program in Denmark\textsuperscript{11}. As with the Danish participants, our mean age was in the early 60s, most participants were overweight or obese, had knee OA and were female. Notably, patients reported a wide range of pain intensity prior to the start of the program confirming other literature indicating that the program is safe irrespective of age, severity of symptoms and radiographic OA grade\textsuperscript{11,14,37}.

The \textit{Effect} of the program was also supported. Only one participant withdrew from the program and this was due to an increase in general pain as opposed to joint-specific pain. Both the hip and knee participants completing the program achieved a 40% reduction in pain which is slightly greater than the pain reduction reported in the initial Danish pilot study and from the registry data of >7000 individuals\textsuperscript{11}. Also, despite our small sample size, we saw improvements in functional performance, QOL and self-reported physical activity of similar or greater magnitude to these Danish data for both hip and knee participants\textsuperscript{11}. While this study did not use wearables due to budget constraints nor would they be practical in broad national implementation, future work should consider evaluation in a subset of participants with validated wearables to quantify physical activity.

In contrast, to the Danish data, few participants in our sample changed their medication use. The reason for this difference is unclear but it is notable that 74\% of our sample (43/58) compared to less than 60\% of the Danish sample\textsuperscript{11} used medication at baseline despite the two studies having similar baseline pain intensity. Further research is required to understand if
there are prescribing differences and or differences in patient’s perceptions of pain medication use between the countries.

While participants did not report meaningful improvements in self-efficacy, a very large proportion of our participants (>90%), similar to Denmark\textsuperscript{33, 38}, reported benefit from and satisfaction with the program. Given self-efficacy is often considered an underlying mechanism of behavior change\textsuperscript{39}, we are unsure why we saw so little change. It may be that the baseline scores were already quite high. We note also that while there were significant changes in self-efficacy in the Danish pilot study\textsuperscript{33}, the magnitude of the change score decreased as additional data were available such that the annual report of 2015\textsuperscript{38} results are similar to those in this study. This raises questions about the possible mechanism underlying the improvement seen in other outcomes. A systematic review identified increased quadriceps and hamstring strength and increased proprioception as possible mediators of improved pain and function in exercise interventions\textsuperscript{40}.

The success of Implementation of the program was demonstrated by our fidelity outcomes where we observed that the components of the GLA:D\textsuperscript{TM} Canada program were delivered as intended. We specifically observed the attention paid to ensuring proper form/alignment in the conduct of the exercises by therapists and participants, and were able to observe and understand the evolution of program delivery processes and learnings of the therapists over time. As described in the results, valuable concrete strategies were used to adapt program delivery that will inform and support implementation at other sites.

Finally, in the short-term, Maintenance was demonstrated in that almost 90% of participants reported using the information on a daily basis. These results are similar to those
reported in the Danish registry annual report of 2015\(^{38}\) and are encouraging. However, it will be critical to monitor use of the information and outcomes over the longer term.

While the results of this feasibility study are very encouraging, they need to be interpreted in the context of the study limitations. First, as this was a feasibility study and our goal was to demonstrate some efficacy, we did not have a control group\(^ {41}\). Also, we report only short-term follow-up and it will be critical to follow these individuals through 1 year to evaluate if these patient-level outcomes are maintained. We had a targeted group of people recruited through the single assessment center that was a partner in the project. Their implementation readiness may not be representative of implementation in other sites and the therapist experience in providing NM group-based exercise may exceed that in other sites. Additionally, reliability of interview transcript coding was not undertaken such that the interpretation of the program adaptations and experiences working with the participants were based on a single coder. Also, due to the relatively short wait time to surgery once a patient was assessed in the clinic, we excluded participants who were surgical candidates from this study. Although there is evidence of benefit in the pre-habilitation context\(^ {42}\) and possible diversion from joint replacement surgery\(^ {43}\), these results cannot be extrapolated to these contexts. Finally, people were offered non-operative care for their hip or knee OA without monetary cost for the program and, given the limited public funding for rehabilitation, the majority of OA patients will need to seek care through the private sector with associated program costs. Our prior work, however, suggested that a large proportion of people would be willing to pay a nominal fee to attend such a program\(^ {44}\) and this was confirmed in this study where more than half the individuals indicated they would be willing to pay more than $250 Canadian.
Future work will need to evaluate Adoption. Uptake and delivery of the program in multiple sites providing access to evidence-based care for people with the spectrum of severity of hip and knee OA will be a critical marker of implementation success. This work is ongoing as GLA:D™ Canada is implemented and evaluated nationally (http://gladcanada.ca/). While most implementation sites are in the private sector where patients pay out of pocket or through third party insurance, there are a few publically funded sites offering the program.

In conclusion, the positive results from this feasibility study supported implementing the GLA:D™ Canada program provincially and nationally. While the work provides insights to support implementation elsewhere, it will be critical to monitor program implementation to ensure program quality, participant outcomes and implementation success. Using a framework such as RE-AIM provides important guidance to ensure all relevant outcomes are evaluated as the program is implemented more broadly.
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Conflict of Interest

Roos and Skou are the founders of GLA:D™ which is a not-for-profit initiative hosted at the University of Southern Denmark.

Roos is the Deputy Editor of Osteoarthritis & Cartilage.

Skou is Associate Editor for the Journal of Orthopedic & Sports Physical Therapy.

Davis is Co-chair and McGlasson is Executive Director of Bone and Joint Canada, the Knowledge Translation arm of the Canadian Orthopaedic Foundation which holds the Canadian License for GLA:D™.

Davis is the Associate Editor of Osteoarthritis & Cartilage.

McGlasson is the Executive Director of Bone and Joint Canada.

Author Contributions

Obtain Funding: DK and AMD

Study Design and proposal: AD, DK, ER, STS, LL, SR
Study oversight: AMD, DK, RW

Data analysis: AMD, RW

Data interpretation: AMD, RW, DK, ER, SK, LL, SR, RM

Manuscript review: AMD, RW, DK, ER, SK, LL, SR, RM
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14. Ageberg E, Nilsdotter A, Kosek E, Roos EM. Effects of neuromuscular training (NEMEX-TJR) on patient-reported outcomes and physical function in severe primary hip or knee


Appendix 1: Semi-structured interview guide for therapist interviews

1. Please tell me about your experiences providing the education and exercise program to people with hip/knee OA.
   
   **Probes:**
   - What did you like about the program?
   - What worked well?
   - What challenges were encountered providing the program?
   - What would be your advice to others to avoid identified challenges?

2. Is there anything you wish you had known that would have helped you in delivering the program?
   
   **Probes:** consider asking about the following areas…
   - Training you received to deliver the program
   - Processes or operationalization of organizing program delivery
   - Additional knowledge or supports to provide the patient education
   - Additional knowledge or supports to provide the patient exercise component

3. If other therapists were going to start providing the program, what advice would you give them?

4. If a facility manager were to ask you about implementing the program, what advice would you offer?
   
   **Probes:**
   - What suggestions or recommendations would you offer related to educating and preparing the therapists to deliver the program?
   - What suggestions or recommendation would you provide concerning the logistics of program delivery for the facility?

5. Is there anything else you’d like to tell me about the program and its delivery?
Table 1: Mapping of the Study Outcomes to the RE-AIM Implementation Evaluation Framework

<table>
<thead>
<tr>
<th>Framework Concept and or possible outcome metric concepts</th>
<th>Outcome Target Level</th>
<th>Outcomes used in the current study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reach</strong></td>
<td>The target population: Absolute number, proportion and representativeness of those willing to participate in the intervention or program</td>
<td>Individual</td>
</tr>
<tr>
<td><strong>Effectiveness/ Efficacy</strong></td>
<td>Relevant patient outcomes, including but not restricted to quality of life and cost</td>
<td>Individual</td>
</tr>
<tr>
<td><strong>Adoption</strong></td>
<td>Absolute number, proportion, and representativeness of settings and health professionals willing to initiate the program</td>
<td>Organization/service system and provider level</td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td>Consistency of delivery as intended, adaptations made during delivery and incremental and implementation costs</td>
<td>Organization/service system and provider level</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>Individual level effectiveness and efficacy outcomes and organizational level outcomes are maintained over the longer term</td>
<td>Individual and organization/service system and provider level</td>
</tr>
</tbody>
</table>
Table 2: Sample Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Hip (n=22)</th>
<th>Knee (n=36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean, sd)</td>
<td>62.9, 8.7</td>
<td>69.9, 9.0</td>
</tr>
<tr>
<td>Sex (n, %): Male</td>
<td>5 (22.7)</td>
<td>8 (22.2)</td>
</tr>
<tr>
<td>Female</td>
<td>17 (77.3)</td>
<td>28 (77.8)</td>
</tr>
<tr>
<td>Marital status (n, %):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/living with partner</td>
<td>14 (63.6)</td>
<td>21 (58.3)</td>
</tr>
<tr>
<td>Other</td>
<td>8 (36.4)</td>
<td>15 (41.7)</td>
</tr>
<tr>
<td>Education (n, %):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;College/university</td>
<td>2 (9.1)</td>
<td>6 (16.7)</td>
</tr>
<tr>
<td>College/university</td>
<td>20 (90.9)</td>
<td>30 (83.3)</td>
</tr>
<tr>
<td>Employment status (n, %):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working full or part-time</td>
<td>6 (27.3)</td>
<td>6 (16.7)</td>
</tr>
<tr>
<td>Not working</td>
<td>3 (13.6)*</td>
<td>2 (5.5)**</td>
</tr>
<tr>
<td>Retired</td>
<td>11 (50.0)</td>
<td>25 (68.4)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (9.1)</td>
<td>3 (8.3)</td>
</tr>
<tr>
<td>BMI: Normal</td>
<td>14 (63.6)</td>
<td>14 (38.9)</td>
</tr>
<tr>
<td>Overweight</td>
<td>4 (18.2)</td>
<td>14 (38.9)</td>
</tr>
<tr>
<td>Obese</td>
<td>4 (18.2)</td>
<td>8 (22.2)</td>
</tr>
</tbody>
</table>

*2 not working and receiving benefits and 1 not working but looking for work

**1 not working and receiving benefits and 1 not working but looking for work
Table 3: Effectiveness/Efficacy Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Hip Pre (n=22) mean, sd</th>
<th>Hip Post (n=22) mean, sd</th>
<th>Mean change</th>
<th>95% CI change</th>
<th>Knee Pre (n=36) mean, sd</th>
<th>Knee Post (n=36) mean, sd</th>
<th>Mean change</th>
<th>95% CI change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numeric Pain Rating Scale (0-10)</td>
<td>4.6, 1.8</td>
<td>2.7, 2.1</td>
<td>-1.9</td>
<td>-2.9, -0.9</td>
<td>5.2, 1.9</td>
<td>2.9, 1.8</td>
<td>-2.1</td>
<td>-2.7, -1.5</td>
</tr>
<tr>
<td>HOOS/KOOS (0-100):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>61.5, 14.2</td>
<td>70.3, 14.0</td>
<td>8.8</td>
<td>4.7, 12.9</td>
<td>59.7, 13.9</td>
<td>68.7, 13.4</td>
<td>9.0</td>
<td>5.4, 12.5</td>
</tr>
<tr>
<td>ADL</td>
<td>67.1, 17.5</td>
<td>79.2, 12.5</td>
<td>12.0</td>
<td>6.3, 17.8</td>
<td>67.9, 16.7</td>
<td>74.4, 18.1</td>
<td>6.8</td>
<td>2.3, 11.3</td>
</tr>
<tr>
<td>Sport and Recreation</td>
<td>39.3, 21.8</td>
<td>49.2, 25.1</td>
<td>9.9</td>
<td>2.7, 17.1</td>
<td>26.3, 22.5</td>
<td>34.4, 26.6</td>
<td>5.4</td>
<td>0.7, 11.4</td>
</tr>
<tr>
<td>QOL</td>
<td>37.0, 17.7</td>
<td>48.8, 18.4</td>
<td>11.7</td>
<td>3.7, 19.8</td>
<td>37.1, 12.1</td>
<td>44.6, 15.3</td>
<td>7.3</td>
<td>2.9, 11.6</td>
</tr>
<tr>
<td>30 second chair stand* (count)</td>
<td>10.9, 2.8</td>
<td>15.0, 3.9</td>
<td>4.1</td>
<td>&lt;0.0001**</td>
<td>9.9, 2.6</td>
<td>12.6, 3.3</td>
<td>2.7</td>
<td>&lt;0.0001**</td>
</tr>
<tr>
<td>40 meter walk test* Speed (m/sec)</td>
<td>1.6, 0.4</td>
<td>1.9, 0.4</td>
<td>0.3</td>
<td>0.2, 0.4</td>
<td>1.4, 0.3</td>
<td>1.7, 0.4</td>
<td>0.2</td>
<td>0.1, 0.2</td>
</tr>
<tr>
<td>Self-Efficacy (1-10)</td>
<td>7.7, 2.6</td>
<td>9.1, 2.4</td>
<td>1.4</td>
<td>0.1, 2.4</td>
<td>6.9, 2.5</td>
<td>8.6, 2.5</td>
<td>0.6</td>
<td>-0.2, 1.5</td>
</tr>
</tbody>
</table>
CI=confidence interval; HOOS=Hip disability and Osteoarthritis Outcome Score; KOOS=Knee injury and Osteoarthritis Outcome Score; ADL=Activities of Daily Living; QOL=Quality of Life

*3 individuals completed only 8 exercise sessions and did not have 3 month functional tests. These results are based on 20 and 35 hip and knee OA patients respectively

**Wilcoxon signed-rank test p-value
Table 4: Fidelity Observation Results

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Not met</th>
<th>Partially met*</th>
<th>Completely met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Therapist Factors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct, clear instructions to participant</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Provides necessary supervision</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Interactions with participants are meaningful/purposeful (e.g. eye contact, feedback, ongoing communication)</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Session completed in allotted time</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td><strong>Participant Factors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates understanding of instructions by therapist</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Accepts direction/feedback</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Engagement in exercises</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><strong>External Factors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequacy of space</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Number of attendees</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

*Occurred within the same observation where space was limited given the number of participants in one class; 4 participants had attended <4 exercise sessions
Figure 1: Flow diagram of patients participating in this study