Is Innovation in the Details: What Have we Learned From the Band-Frail Project?

Age-Well National Innovation;
Age Well, Canada’s Technology & Aging Network;
Advancing Policies and Practices in Technology and Aging;
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Population is aging at a faster rate in New Brunswick.

The prevalence of diabetes in New Brunswick is higher than the national average.

About ¼ (25%) of adults above 65 years have diabetes.

National average for Diabetes is 8.8%

- 2019: 12%
- 2029: 16%

Prevalence and Projection of Aging

<table>
<thead>
<tr>
<th>Year</th>
<th>Canada</th>
<th>New Brunswick</th>
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<tbody>
<tr>
<td>2018</td>
<td>16.8</td>
<td>20.8</td>
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<tr>
<td>2038</td>
<td>23.0</td>
<td>31.4</td>
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Impact of Diabetes & Frailty

Hospitalized with Cardiovascular diseases (3X)
- 30% of strokes
- Leading cause of blindness

Hospitalized with end-stage renal disease (12X)
- 40% of heart attacks
- 50% of kidney failure requiring dialysis

Non-traumatic lower limb amputation (20X)
- 70% of all non-traumatic leg and foot amputations

Lifespan reduced by as much as 15 years

Up to 25% of people with diabetes have Frailty

People with Diabetes are less likely to improve from a frail to a pre-frail compared to people without Diabetes

Diabetes Canada Estimated Prevalence and Cost of Diabetes, 2022

Cardiometabolic Exercise and Lifestyle Lab

Background: Genesis of Band-Frail Study

An evaluation of the effectiveness of a multi-modal intervention in frail and pre-frail older people with type 2 diabetes - the MID-Frail study: study protocol for a randomised controlled trial


Abstract
Background: Diabetes, a highly prevalent, chronic disease, is associated with increasing frailty and functional decline in older people, with consequent personal, social, and public health implications. We describe the rationale and methods of the multi-modal intervention in diabetes in frailty (MID-Frail) study.

Methods/Design: The MID-Frail study is an open, randomised, multicentre study, with random allocation by clusters (each trial site) to a usual care group or an intervention group. A total of 1,718 subjects will be randomised with each site enrolling on average 14 or 15 subjects. The primary objective of the study is to evaluate, in comparison with usual clinical practice, the effectiveness of a multi-modal intervention (specific clinical targets, education, diet, and resistance training exercise) in frail and pre-frail subjects aged ≥70 years with type 2 diabetes in terms of the difference in function 2 years post-randomisation. Difference in function will be measured by change in a summary ordinal score on the short physical performance battery (SPPB) at 1 at least one point. Secondary outcomes include daily activities, economic evaluation, and quality of life.

Discussion: The MID-Frail study will provide evidence on the clinical, functional, social, and economic impact of a multi-modal approach in frail and pre-frail older people with type 2 diabetes.

Trial registration: ClinicalTrials.gov: NCT0164541.

Keywords: Multi-modal intervention, Frail, Pre-frail, Type 2 diabetes.

Background
Diabetes has a high prevalence in ageing populations, affecting approximately 20% of people aged 70 years or over. It is anticipated that by 2050 the number of cases of diabetes will have increased by fourfold in people older than 70 years [1]. Diabetes is associated with increasing frailty and functional decline in older people [2]. Frailty is defined as a clinical syndrome in which three or more of the following criteria are present: unintentional weight loss (≥4.5 kg in past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity [3]. Diabetes has serious personal and social consequences, and is a significant public health burden in terms of rising health care costs. In Spain, annual direct health care costs have been estimated at 2.5 billion euros [4]. In recent studies of older people, up to 28% of those with diabetes required some help with activities of daily living, compared with 16% of those without the condition [5]. This functional decline can be explained in only half of the cases by the classical complications of the disease, such as coronary artery disease, stroke, and peripheral vascular

7 European Countries, 74 sites across countries
Background: Genesis of Band-Frail Study

Group comparisons

Primary Exposure

Intervention + Education

Usual care

Primary Outcome

1. Balance Tests
   - Side-by-Side Stand
     Feet together side-by-side for 10 sec
     10 sec (1 pt)
     10 sec (+0 pt)
     < 10 sec (0 pt)
     Go to 4-Meter Gait Speed Test
   - Semi-Bendon Stand
     Heel of one foot against side of big toe of the other for 10 sec
     10 sec (+1 pt)
     10 sec (+0 pt)
     < 10 sec (+1 pt)
     Go to 4-Meter Gait Speed Test
   - Tandem Stand
     Feet aligned heel to toe for 10 sec
     10 sec (+2 pt)
     3-9.90 sec (+1 pt)
     < 3 sec (+0 pt)

2. Gait Speed Test
   Measures the time required to walk 4 meters at a normal pace (use best of 2 times)
   - 4.82 sec: 4 pt
   - 4.83-6.20 sec: 3 pt
   - 6.21-8.70 sec: 2 pt
   - > 8.7 sec: 1 pt
   - Unable: 0 pt

3. Chair Stand Test
   Participants fold their arms across their chest and try to stand up once from a chair
   - Pre-test
     - able: < 11.10 sec: 4 pt
       11.10-15.60 sec: 3 pt
       15.61-16.60 sec: 2 pt
       > 16.6 sec: 1 pt
     - unable: > 60 sec or unable: 0 pt
   - 5 repeats
Background: Genesis of Band-Frail Study

Results: from Mid-Frail Study

- Increased more than 1-pt (81% likely)
- Saved about $1000/patient/year
- Glycemic control
  Blood pressure (better intervention vs Ucare)

The Mid-Frail study = 1) improvements clinically relevant, 2) was cost-effective, 3) improved other CMRF.

(J. cach., sarco. & muscle 2019;10:721-733)
Band-Frail Study: Designing the Proposal
December 23th 2018

University of New Brunswick
Dalhousie University
University of Sherbrooke
University of Moncton
University of Toronto

MID-Frail, PI
Diabetes Action Canada
Certified Diabetes Educators
Canadian Frailty Network
NBHRF; NB-IRDT; SPOR-MSSU

Government of NB
Horizon Health Network
Vitalité Health Network

INCREASING INDEPENDENCE, QUALITY OF LIFE, AND PROMOTING HEALTHY LIFESTYLES
Band-Frail Study: Broad Objective

Primary and short-term objective:

• To test if physical function, HbA1c, psychological and social health improve in participants with T2DM and frailty.

Secondary and long-term objectives:

• To test long-term outcomes using provincial administrative data in a follow-up of 1, 3, 5, and 10 years following the intervention.

• To perform a cost-effective analysis of the Band-Frail study.

• To develop a similar initiative for other NB seniors living with frailty, and to organize an Advisory Committee to contribute to the implementation of the Band-Frail program across Canada.
Band-Frail Study: Participants and Recruitment

- Aged 65 years and older
- With T2DM
- Pre-frail or frail individuals

- 5 Health Zones in NB
- 14 Sites across NB
- N=125 Finished
- N=175 participants

Frailty Criteria

(1-2 Criteria = Pre-Frail; ≥ 3 Criteria = Frail)

<table>
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<tr>
<th>Criteria</th>
<th>Definition</th>
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<td>Weight loss:</td>
<td>Self-reported unintentional weight loss of 4.5kg during last year</td>
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<td>Exhaustion:</td>
<td>Based on the CSEP-D Depression Scale</td>
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<td>Weakness:</td>
<td>Measured using grip strength (lowest 20% percentile)</td>
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<td>Slowness:</td>
<td>Measured using the timed up and go test (TUG &gt; 19 seconds)</td>
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<td>Physical activity (PA):</td>
<td>Measured with questionnaire (hardly ever/never for energetic PA or moderate PA)</td>
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Band-Frail Study: Intervention

- Delivered by Diabetes Educators
- Program of 16 weeks
- Perform 2 times per week
- Education received once per week
Primary Outcomes
Preliminary Data

- SPPB Guide
- Questionnaire SF-36
- Muscle Strength
- Frailty level Fried Scale
- HbA1c (Glycemia)
- Interviews
Band-Frail Results: Physical Functions & Frailty Status

Conclusions

- Band-Frail Program improves Physical Functions
- Band-Frail Program improves Muscle Strength
- Band-Frail Program improves Power
- Band-Frail Program reduces Frailty Status
Band-Frail Results: SF-36 Domains

The figure illustrates the change in SF-36 scores for Physical Functioning, Role Functioning – Physical, and Energy/Fatigue domains before and after the intervention. The black bars represent pre-intervention scores, while the red bars indicate post-intervention scores. All three domains showed a significant improvement with p-values less than 0.001. The improvements are statistically significant.
Band-Frail Results: SF-36 Domains

![Bar chart showing changes in SF-36 domains before and after intervention]

- **Emotional Well Being**: Pre-intervention score is 75,Post-intervention score is 90, p=0.029
- **Social Functioning**: Pre-intervention score is 75, Post-intervention score is 90, p=0.017
- **Health Change**: Pre-intervention score is 45, Post-intervention score is 75, p<0.001
Band-Frail Results: Glycemia

**Conclusions**

- Band-Frail Program improves Physical Functions;
- Band-Frail program improves health problems related to physical limitations, energy/fatigue, emotions & well-being and health problem related to social norms;
- Band-Frail program improves perceived general health
- Band-Frail improves HbA1c (Glycemia)
What goals did you have when you joined the programme?

(...) I had been a diabetic for 15 years, (...) my doctor suggested maybe it would be time for insulin and well we travelled 10, 12, 15 weeks a year I don’t want to be bothered with insulin. (...) 

(...) I had a pain that started to shoot down my left arm for no reason behind my shoulder blade and I thought these exercises would help to get rid of that. I’ve been going to the massage therapist to try and work it. (...) Those are the two reasons that I took the program.

Did you reach your goals with the program?
I haven’t had to go to massage therapy since. (...) it was gone.
And my blood sugar went down

Did you enjoy your experience with the program?
Absolutely it was very very good.
Conclusions

Are we using “Invention” and “Innovation” interchangeably?

“Innovation, can refer to something new or to a change made to an existing product, idea, or field”.

-Travel back in time

-Changing current the practices