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MTL2018

Establishing a Research Agenda for Behavioural Trials: Results from the IBTN Prioritisation Project

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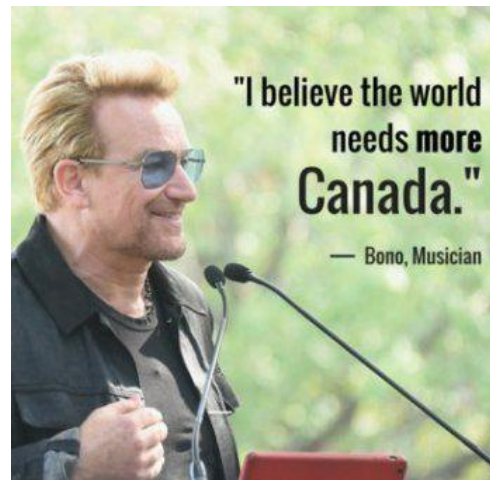
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**Chair in Innovative
Behavioural Trials**





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- Build collaborations between Canadian and Irish Centres of Excellence in health behaviour interventions and trials, ultimately to improve public health in both Ireland and Canada.
- Progress the work of the International Behavioural Trials Network.





Simon
Bacon



Kim
Lavoie

- Facilitate the global improvement of the quality of behavioural trials
- Provide networks and capacity to undertake more and higher quality trials
- Develop a repository for existing recommendations, tools, and methodology papers on behavioural trials and intervention development

- Research prioritisation for Behavioural Trial Research
- Seek further funding



Research agenda for IBTN

- Previously identified methodological issues include: **intervention development and piloting, intervention reporting, identifying suitable comparison groups, selection of appropriate outcome measures and intervention fidelity** (Bacon et al., Current Cardiovascular Risk Reports. 2015;9(1):427.).
- Can we achieve a wider consensus on priority issues to progress the research agenda of the IBTN?



Aim


- To conduct an international, Delphi consensus study to identify and achieve consensus on priorities for methodological research in behavioural trials among IBTN members.





STUDY PROTOCOL

An international, Delphi consensus study to identify priorities for methodological research in behavioural trials: A study protocol [version 1; referees: 1 approved]

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v1

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Open Peer Review

Referee Status: 



Method

1. Expert topic generation: Core IBTN members (n=15) invited to generate topics

2. Finalise topic 'long list': Research Prioritisation Team

3. Two-phase eDelphi survey to all IBTN members to rate and rank importance of topics: N1=306 & N2=77

1. Expert topic generation

1. Molly Byrne
2. Jenny McSharry
3. Simon Bacon
4. Kim Lavoie
5. Ken Friedland
6. Linda Collins
7. Paul Montgomery
8. Justin Presseau
9. Gregory Ninot



**135 items
generated**



2. Finalise topic long list

Category	Items Generated	Originally Proposed Item	Suggestions from Kim	Suggestions from Simon	Comments from Simon	Suggested 2nd draft wording (20th July 2017)
Intervention Development	Using theory and evidence to inform interventions (MB)/Does theory matter? A meta-analysis by Prestwich et al. (Health Psychology 2014 May;33(5):465-474) suggests that grounding interventions in popular theories doesn't make any difference in treatment effectiveness research on physical activity and healthy eating interventions. Similar studies are needed in other areas of behavioural intervention research. (KF)/The role of behaviour change theory: use of existing demonstrated models vs. new hypotheses (JP)/Dual process approaches to behaviour change: reflective vs impulsive/automatic intervention techniques	Value of theory in intervention development				Value of theory in intervention development
	Systematic approaches to move from evidence to intervention specification (MB)/Need to develop methods suitable for modelling behavioural intervention components (MB)/Experimental approaches to test likelihood of effectiveness of components (MB)/Are behaviour change interventions developed using systematic approaches (e.g. The Behaviour Change Wheel) more effective than other behaviour change interventions? (JMS)/Do interventions developed using systematic methods (e.g. Behaviour Change Wheel) differ from those developed using more general it seemed like a good idea principles? (JMS)/Would two groups developing an intervention using the same exploratory data and moving through the same systematic approach stages develop similar interventions? (JMS)/Adequaterigorous intervention development (use of a framework like ORBIT) (KL)/Sources of evidence to inform intervention development: lots of advice of different types of	Systematic approaches to move from evidence to intervention components	Using systematic approaches...			

Intervention Fidelity/ Participant Adherence	Treatment integrity: "interventionist" quality and training (KL)	Qualification/training of interventionists				Qualification/training of interventionists
	Intervention fidelity – how to maximise adherence to intervention protocol? (ME)	Optimising intervention				Optimising intervention fidelity
	Assessment and reporting of intervention fidelity (KL)/ Intervention fidelity – how to measure/assess? (ME)	Assessment of intervention fidelity				Assessment of intervention fidelity
	Treatment fidelity (SB)					
	Recruitment and retention in trials (KL) /Participant burden and attrition: Which parameters tend to increase attrition in RCTs? E.g., too many measures? Too many /inconvenient lab visits? Too many intervention-related demands? (KF) Fidelity/Adherence	Recruitment and retention in trials	Participant recruitment and retention	could extend beyond trial designs	If it was extended to beyond trials I would see this as being out of scope	RCT participant recruitment and retention
	Intervention fidelity cut-off – what is minimum level to qualify as participating in the intervention? (ME)					
Pilot/Feasibility	Establishing cut-off/stop-start guidelines for pilot behavioural trials – how to decide when a behavioural trial is likely not to be feasible (ME)	Establishing criteria for progressing from pilot to full RCT				Establishing criteria for progressing from pilot to full RCT
	The size of pilot and feasibility studies (SB)	Sample size calculations for pilot				Sample size calculations for pilot trials
	When to use a RCT design for pilot and feasibility studies (SB)	Novel designs for piloting	Novel pilot study designs			Novel designs for piloting interventions
Reporting	Systematic, internationally standardised methods of reporting behavioural trials (JMS)/Inadequate reporting (KL)/Dissemination of good practice guidelines and frameworks (SB)/The correct mechanism for reporting trials – what CONSORT statement to use (SB)	Standardise d methods and checklist for reporting behavioural trials	Standardizing methods for reporting behavioural trials	checklists might be one method	I agree with the idea of having this as a standardised method for reporting behavioural trials, and wouldn't include a checklist.	Standardizing methods for reporting behavioural trials
	Lack of common ontology/language for defining interventions/intervention "ingredients" (KL)/Heterogeneity of description of behavioural intervention in so many journals (GN)	Reporting intervention content		should this be subsumed into above?	I think that this item and the one below could be collapsed to: Reporting intervention and comparison group(s) content	Reporting intervention and comparison group(s) content
	Specifying intervention content and control group content (ME)/Use of behaviour change techniques to describe intervention and control groups – how to measure and describe BCT dose, intervention delivery mode. (MB)/How best can we describe the content and non-specific factors associated with control groups? Consistent usage of terminology within and between fields (SB)	Reporting comparison group content		should this be subsumed into above?		
		Terminology	Using common terminology and definitions?		I would make a case for this being covered by the items above. If there are general reporting standards for the trial and	



Categories	Topics
Intervention Development	1. Using theory in behavioural intervention development
	2. Use of systematic approaches to move from evidence to intervention components
	3. Specifying intervention components
	4. Exploring impact of mode of intervention delivery
	5. Tailoring interventions to specific populations and contexts
Comparison Group	6. Selection of suitable comparison group(s) within trials
	7. Contamination between study arms (intervention and comparison) within trials

**Final 'long list'
(12 categories,
33 items)**

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Categories	Topics
Intervention Development	1. Using theory in behavioural intervention development
	2. Use of systematic approaches to move from evidence to intervention components
	3. Specifying intervention components
	4. Exploring impact of mode of intervention delivery
	5. Tailoring interventions to specific populations and contexts
Novel Trial Designs	19. Development of novel research designs to test behavioural interventions as alternatives to, or to complement, standard RCTs
Outcomes	22. Determining clinically significant changes in outcomes within trials
	23. Selecting appropriate behavioural outcomes for trials
	24. Relationship between behavioural outcomes and clinical/other outcomes
	25. Determining ideal timing of outcome measurement within trials
	26. Measurement of process(es) of change or mechanisms of action within interventions
Stakeholder engagement	30. How to optimise stakeholder engagement in behavioural trials research
	31. Incorporating stakeholder input in intervention development and delivery
	32. Testing the impact of stakeholder engagement in behavioural trial research
Development of behavioural science and theory	33. Trials research to test and develop behavioural theories

3. E-Delphi survey

- **Survey 1:** rate how important each of 33 items is on 9 point scale, where 9 is very important.
- Rank 'top 5' research topics.
- **Survey 2:** respondents see how others voted and reminder of their own results, asked to rate and rank again



E-Delphi survey

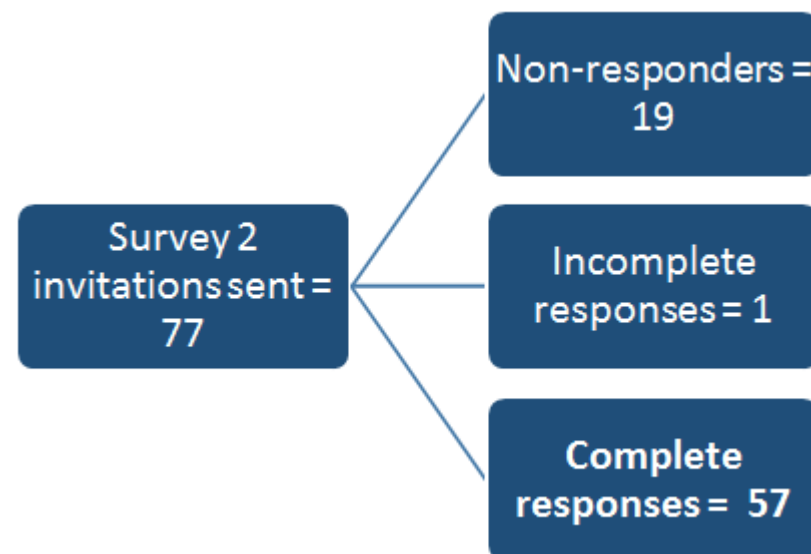
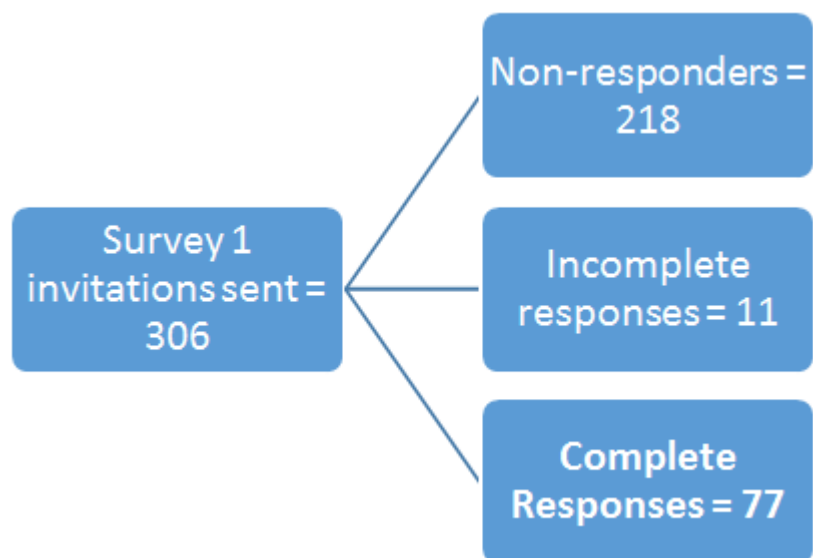


Table 1: Professional background and demographic data for survey completers:

	Survey round 1 <i>n</i> =77	Survey round 2 <i>n</i> =57
Gender		
Male	23 (29.9%)	17 (29.8%)
Female	53 (68.8%)	39 (68.4%)
Other	1 (1.3%)	1 (1.8%)
Professional Position		
University student (undergraduate/postgraduate)	17 (22.1%)	12 (21.1%)
Academic staff (e.g. researchers, lecturers, professors)	49 (63.6%)	38 (66.7%)
Health care practitioner	2 (2.6%)	1 (1.8%)
Health policy maker or planner	2 (2.6%)	1 (1.8%)
Other	7 (9.1%)	5 (8.8%)
Country of Residence		
Ireland	12 (15.6%)	8 (14.0%)
Israel	1 (1.3%)	1 (1.8%)
Australia	2 (2.6%)	1 (1.8%)
Netherlands	1 (1.3%)	1 (1.8%)
Portugal	1 (1.3%)	1 (1.8%)
Sweden	1 (1.3%)	1 (1.8%)
United Kingdom	7 (9.1%)	5 (8.8%)
United States of America	12 (15.6%)	9 (15.8%)
Brazil	1 (1.3%)	1 (1.8%)
Canada	33 (42.9%)	25 (43.9%)
China	1 (1.3%)	1 (1.8%)
Columbia	1 (1.3%)	1 (1.8%)
France	4 (5.2%)	2 (3.5%)
Age Group		
18-30 years	18 (23.4%)	14 (24.6%)
31-40 years	28 (36.4%)	19 (33.3%)
41-50 years	17 (22.1%)	11 (19.3%)
51+ years	14 (18.2%)	13 (22.8%)
Years of experience in trials of behavioural interventions		
Less than 1 year	12 (15.6%)	8 (14.0%)
1-5 years	27 (35.1%)	19 (33.3%)
6-10 years	18 (23.4%)	14 (24.6%)
10+ years	20 (26.0%)	16 (28.1%)

Survey 1 & 2 item ratings

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Research items	Survey 1			Survey 2		
	Mean	SD	Rank	Mean	SD	Rank
• Specifying intervention components	7.81	1.31	3	8.33	.81	1
• How to disseminate behavioural trial research findings to increase implementation	7.83	1.45	2	8.3	.93	2
• Methods for ensuring that behavioural interventions are implementable into practice and policy	7.75	1.52	4	8.21	.90	3
• Use of systematic approaches to move from evidence to intervention components	7.9	1.19	1	8.11	.98	4
• Selecting appropriate behavioural outcomes for trials	7.66	1.23	6	8.04	.68	5
• Tailoring interventions to specific populations and contexts	7.69	1.66	5	7.96	1.20	6

Table 2: Importance ratings for individual research items in surveys 1 and 2, ordered by survey 2 priority rankings (possible score range 1-9, 1= lowest importance, 9 = highest importance)

Survey 1 & 2 'Top 5' items

Item name	Weighted ranking score	Overall Rank	Weighted ranking score	Overall Rank
	Survey 1	Survey 1	Survey 2	Survey 2
• Tailoring interventions to specific populations and contexts	94	1	109	1
• Methods for ensuring that behavioural interventions are implementable into practice and policy	72	5	97	2
• Specifying intervention components	80	2	75	3
• Use of systematic approaches to move from evidence to intervention components	72	5	73	4
• Development of novel research designs to test behavioural interventions as alternatives to, or to complement, standard RCTs	74	4	67	5
• How to disseminate behavioural trial research findings to increase implementation	75	3	63	6

Table 3: Weighted ranking of participant responses to the 'top five' priorities question order by the most highest ranked item in survey 2, 1st pref = 5, 2nd = 4, 3rd = 3, 4th = 2, 5th = 1)

Highest priority topics:

- Understanding and tailoring intervention components:
 - Specifying intervention components (highest rated)
 - Tailoring interventions to specific populations and contexts (highest ranked)
- Intervention implementation:
 - How to disseminate behavioural trial research findings to increase implementation (second highest rated)
 - Methods for ensuring that behavioural interventions are implementable into practice and policy (second highest ranked)



Next steps...?

- Dissemination
 - Where to publish?
 - Further dissemination?
- For IBTN
 - Value in wider behavioural intervention research community engagement?
 - Creating a research agenda for IBTN?
 - Forging international, collaborative projects in priority methodological topics



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