

**Testing a TheoRY-based
MMessage ('TRY-ME'):
A SUB-TRIAL WITHIN A RCT
OF PRINTED EDUCATONAL
MATERIALS (THE OPEM TRIAL)**

JF, JG, MZ, MPE, SG, GG, MJ, JP, JT

Background: Trial Context

- 2x2 factorial cluster randomised trial
- Participants randomised to one of 4 groups
 - Control
 - Short directive messages only
 - Long discursive messages only
 - Both short and long messages
- Messages are embedded in the ***informed*** newsletter, a free, quarterly publication produced by the Institute for Clinical Evaluative Sciences (ICES)
- Clinical behaviour: prescription of thiazide diuretics as the first drug treatment for patients with hypertension

Background: Rationale

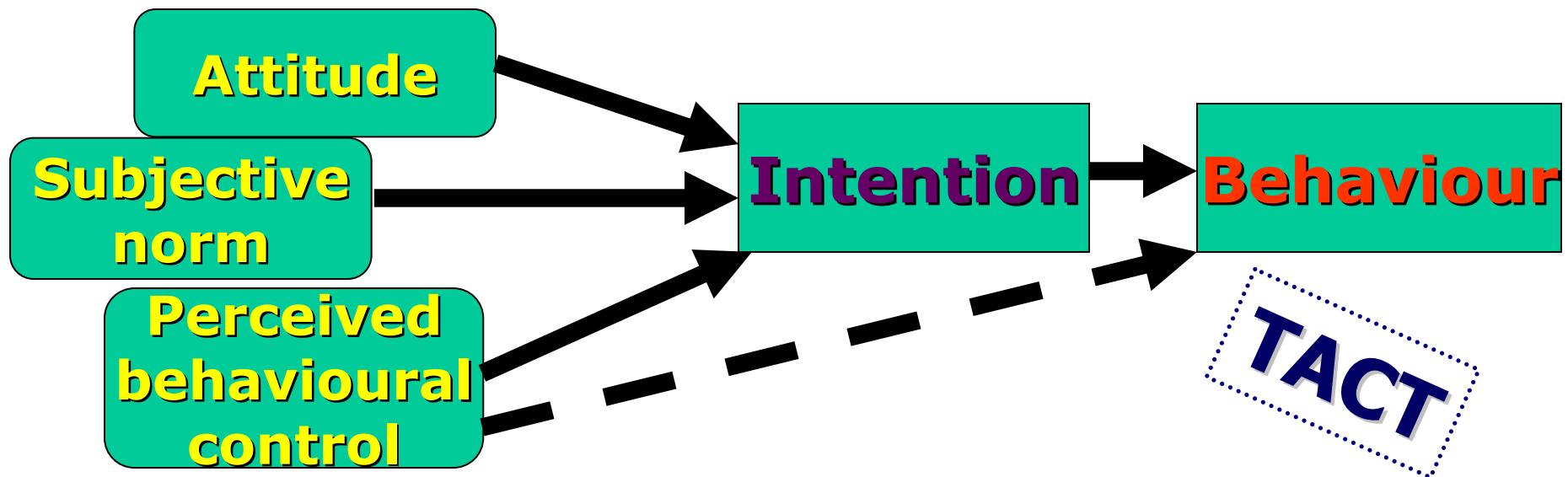
- Current evaluations of behaviour-change strategies provide little insight into:
 - Causal mechanisms
 - Effect modifiers
- This limits generalisability of findings to other clinical problems and contexts
- Need to develop higher-order principles (ie theories) to generate testable hypotheses that apply across a range of clinical contexts
- TRY-ME: Involved constructing the content of brief educational messages using both standard methods and methods informed by theory

Possible theoretical approaches, 1

- Persuasion theory - effects of persuasive messages on attitude change
 - Credibility of the message source
 - Features of the message based on assumed depth of processing
- Principles already represented in the three replications of the OPEM trial
- Persuasion theory is silent about the effects of attitude change on behaviour

Possible theoretical approaches, 2

- Theories that specify the links between attitudes and behaviour
- Additional predictor variables and a mediating variable (intention)
- The Theory of Planned Behaviour (Ajzen, 1991)



Study Hypotheses

- H1: A message based on the TPB will be more effective in changing prescribing behaviour than a message based on ‘standard’ methods (uninformed by an explicit theoretical basis)
- H2:
 - The TPB variables represented in the theory-based message will be improved among FPs exposed to the theory-based message (compared with the standard message group and the control group) **(Attitude; Subjective Norm; Intention)**
 - The variables not represented in the theory-based message will not show such improvement **(Perceived Behavioural Control)**

Assumptions

- The ‘standard’ method of message construction does not map onto a theory
- The mere presence of a variable in a message will change participants’ cognitions
- The cognitions represented in the message are the one that will affect behaviour change
(ie Attitudes; SN; Intentions; not PBC)

Development of Short Messages

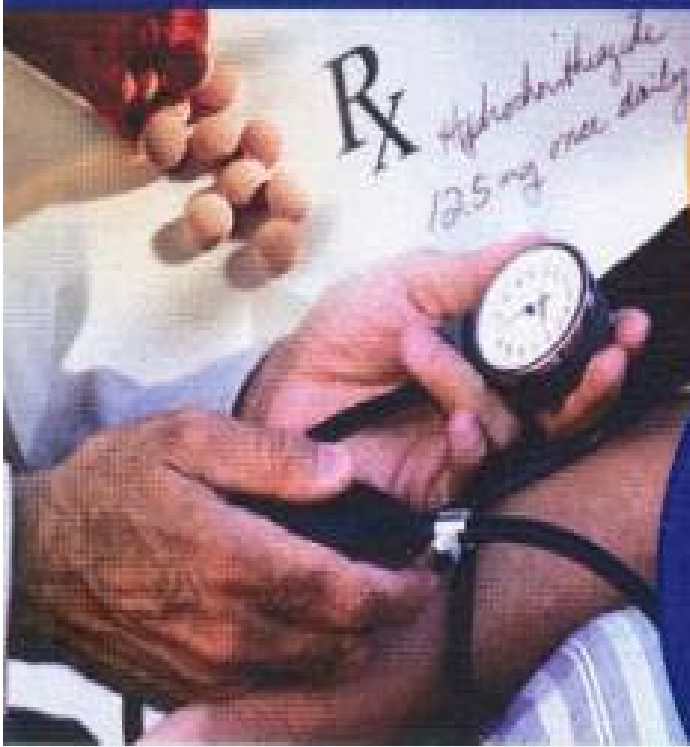
- Two research teams independently developed the wording of the two messages
 - For Message B, psychologists with experience in KT research and clinical researchers experienced in use of psychological theories
 - For Message A, clinical researchers experienced KT research and in the development of short educational messages directed to clinicians

Message Design: Agreed Constraints

- Teams designed the messages to include:
 - Banner
 - Up to 4 bullet points
 - Up to 85 words
 - Key clinical messages
 - Footnotes to key messages on back of card
- Following agreement on message wording, a graphic design consultant formatted the messages using similar styles, font sizes and colours.

Message A ('standard' construction)

Take a new look at **thiazides** for first-line treatment of hypertension



- ✓ BP control equal to all other antihypertensives^{1,2}
- ✓ Better stroke prevention than ACE inhibitors²
- ✓ Better heart failure prevention than calcium channel blockers²

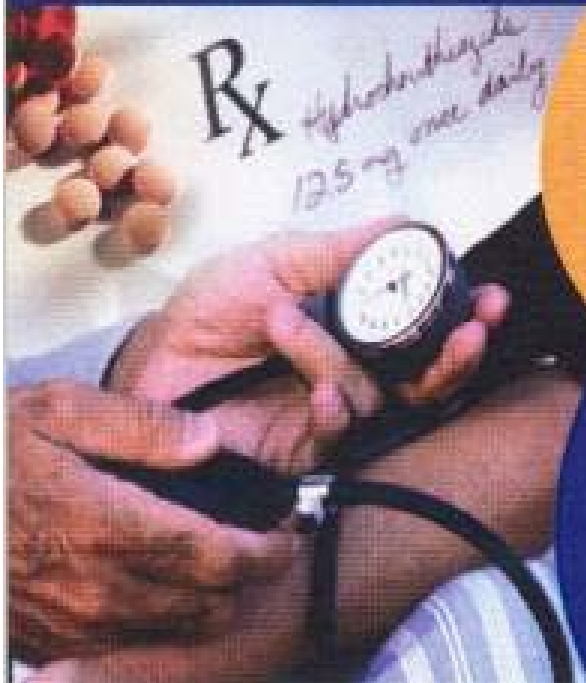
^{1,2} See reverse side

**Make thiazides the first-line choice
for your patients**



Message B (theory based construction)

Prescribe **thiazide diuretics** as the first drug to treat patients with hypertension



- ✓ You will be more effective in lowering your patients' heart failure risk than if you prescribe calcium channel blockers¹
- ✓ You will be more effective in lowering your patients' stroke risk than if you prescribe ACE inhibitors¹
- ✓ You can feel good about giving your patients the most effective treatment¹
- ✓ You will be prescribing one of the most effective drugs as recommended by the Canadian Hypertension Education Program²

^{1,2} See reverse side

Will **YOU** routinely prescribe thiazide diuretics??

Yes

No

informed

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Messages: Summary Features

Message A (standard)

- Banner: 11 words; 69 characters
- Three bullet points
- Words in bullet points: 7; 6; 8
- Key message: 8 words
- Total Words: 40

Message B (theory based)

- Banner: 12 words; 82 characters
- Four bullet points
- Words in bullet points: 19; 17; 12; 18
- Key message: 6 words
- Total Words: 84

Manipulation check

- To test the validity of the intended distinction between theory-based and standard messages
- Members of the Aberdeen Health Psychology group (12 doctoral fellows, post-doctoral fellows and academics; included 9 psychologists) made judgements about each message:
 - What is the target behaviour?
 - How clearly does the message specify the behaviour?
 - Which theoretical constructs are reflected in this message?
- Response formats: confidence or extent ratings to produce continuous scales
- Paired sample t-tests used to test differences between judgements

Manipulation check results, 1

Elements of target behaviour as reported by group members

Element	Standard message	Theory based message
Prescribe	6	11
Choose	1	0
Thiazide	8	10
First	1	3
Drug	1	2
Hypertension	7	7

Manipulation check results, 2

- **Clarity of the behaviour specification** measured on a 7-point scale
- Unnumbered response options with extremes labelled *not at all clearly* (assigned a value of 1) and *extremely clearly* (assigned a value of 7)
- The mean clarity rating was 6.00 ($sd = 1.04$) for the theory based message and 3.83 ($sd = 1.27$) for the standard message
- There was a **significant difference** between these means, $t(11) = 4.29$, $p = .001$ (two-tailed).

Manipulation check results, 3

- **Theoretical constructs** reflected in the messages
 - The mean number of constructs named was 1.92 ($sd = 1.38$) for Message A and 2.92 ($sd = 1.51$) for Message B
 - This difference was statistically significant, $t(11) = 2.25$, $p = .046$ (two-tailed)
- **Certainty ratings** for the named constructs
 - Mean certainty ratings (range 1-7) computed for each responder
 - Four responders did not name any constructs & so did not give certainty ratings (3 for Message A; 1 for Message B)
 - The mean certainty rating across the sample (of 9) was 4.19 ($sd = 1.25$) for Message A and 4.93 ($sd = 1.75$) for Message B
 - The difference between these means was not significant, $t(8) = 1.49$, $p = .175$ (two-tailed)

Manipulation check results, 4

Constructs ranked as highest in **importance** for each message

Construct	Message A	Message B
Attitude/outcome expectancy	4	5
Intention	1	3
Perceived behavior control	1	1
Self-efficacy	0	1
Cure/control	2	0
Decision making	0	1
Persuasion	1	0

Manipulation Check Conclusions

- Although the sample of psychologically –informed responders was small, it appears that they responded to the two messages in reliably different ways
- Perceived **clarity of behaviour specification** and **number of constructs named** were significantly higher for the theory based message
- However, the constructs judged to be highest in importance
 - Included attitudes in both messages
 - Did **not** include subjective norms in either message
 - Included control-related constructs in both messages

Outcome and Process Variables

- Primary outcome. Routinely collected administrative data available within ICES to measure changes in prescription of thiazide diuretics (H1)
- Process measures. The process evaluation survey instrument based on the TPB, administered pre and post intervention (H2)

Planned Analyses

- H1: group differences in prescribing behaviour:
 - t-tests to compare two groups
 - analysis of covariance to compare groups adjusting for differences in baseline performance
- H2 (see OPEM process evaluation study)
 - Test internal reliability of the questionnaire measures using Cronbach's alpha. If internal consistency is <0.7 , we will explore whether we can improve this by omitting any individual item
 - Use One-way Multivariate Analysis of Covariance (followed by univariate tests where appropriate) to test for group differences in scores for attitudes, subjective norms and intentions

Sample size considerations

- For H1 in this two-group design, with a directional hypothesis and assuming equal variances, we need 50 participants per group to achieve 80% power to detect an effect size of 0.5 standard deviations, using a significance level of 5%
- For H2, after adjustment for applying 4 significance tests, we need 63 subjects per group for the same power parameters
- This gives a sample size for the sub-trial of $63 * 2 = 126$. Assuming a 50% response rate for each survey (pre and post intervention), we will sample 252 physicians to achieve this sample size (i.e. 50% or 126 complete the first survey and 50% of these or 63 complete the second survey).

Discussion

- Does the argument logically support the hypotheses?
- Is the manipulation check credible/adequate?
- What is your reaction to the difference between messages? Is this a fatal design flaw?
- Does the analysis plan make sense?
- Sample size calculation: Help!

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