

Research Article

Development of an Intervention for Implementing Immunochemical Faecal Occult Blood Test in General Practice

Jakob Sjøgaard Juul

Department of Public Health, Aarhus University, Denmark

Peter Vedsted

Department of Public Health, Aarhus University, Denmark

Flemming Bro

Department of Public Health, Aarhus University, Denmark

ABSTRACT

Background: The immunochemical faecal occult blood test (iFOBT) may improve colorectal cancer (CRC) diagnostics in general practice.

Aim: The study aimed to develop an intervention to facilitate quick uptake of the iFOBT in general practice.

Methods: The Behaviour Change Wheel was used as the theoretical framework for analysing potential barriers which could make general practitioners (GPs) reluctant towards iFOBT use. An initial intervention model was developed and pilot-tested among GPs in the Central Denmark Region. Finally, the intervention was adjusted according to GPs experiences in the pilot period.

Results: Three elements were found important to facilitate uptake: a flexible guideline on iFOBT use, a participatory peer-based training approach and a test-ordering procedure building on existing routines.

Conclusion: The theory-based approach proved valuable in developing an intervention to facilitate quick uptake of a new test in clinical practice and pilot testing of the intervention possibly prevented a project failure in a large scale study.

Keywords: General practice; Colorectal neoplasms; Occult blood; Pilot projects; Clinical trials

What do we know?

It is difficult to change the clinical behaviour. Knowledge on what works, why and how is essential to ensure successful implementation of new innovations.

What does this paper add?

We present a model for the rapid development of an intervention to facilitate fast uptake of a new test for blood in the stool to be used in general practice. We found that GPs need flexible guidelines and that new test procedures should build on existing routines. A theory-based approach allows a focused development of new interventions, whereas transparency ensures that the findings can be transferred to other settings and situations.

Abbreviations:

CME: Continuous Medical Education; COM-B: Capability Opportunity Motivation-Behaviour; CRC: Colorectal Cancer; GP: General Practitioner; iFOBT: Immunochemical Faecal Occult Blood Test

Background

It is estimated that 75-80% of all colorectal cancer (CRC) diagnoses are found through symptomatic presentation in general practice.^{1,2} Diagnosing CRC at earlier stages is not straightforward as half of patients with CRC present with other symptoms than alarm symptoms.³

The immunochemical faecal occult blood test (iFOBT), which detects blood in stools, may be useful for identification

of CRC in general practice.⁴⁻¹⁰ However, the test is not a part of the Danish GPs' diagnostic tools. To investigate the diagnostic value of iFOBT in general practice a large scale randomised study was planned in the Central Denmark Region.¹¹

The behavioral Change Wheel provides researchers with a framework that allows identification of potential barriers when new health care interventions are developed and implemented. Furthermore, it links identified barriers to specific intervention functions. The model assumes that any change is governed by the individual's capability (C), opportunity (O) and motivation (M) to change behaviour (B) (COM-B).¹² A newly developed intervention model should be pilot-tested and subsequently adjusted before being launched at a large scale.^{13,14} (Table 1).

The aim of this study was to develop an intervention which

Table 1: Identified barriers and planned interventions using COM-B analysis.

Sources of behaviour	Identified barriers	Intervention components	Intervention components to mitigate barriers
Psychological capability	Lack of knowledge about the clinical use of iFOBT	Education Training	GP training course and clinical guideline
Physical capability	-	-	-
Social opportunity	Insufficient support from staff in own practice	Organisational restructuring	Test kit available Training material for staff
Physical opportunity	Unknown or difficult logistic set-up	Environmental restructuring	Easy test ordering
Automatic motivation	Lack of incentives Lack of peer support	Incentives Persuasion Modelling	Remuneration Pilot project Back-up from trade union
Reflective motivation	Lack of motivation	Incentives Education Training	GP training course and Clinical guideline

could be used in a large scale study to facilitate quick uptake of the iFOBT in general practice.

Methods

Design

The development process was divided into three steps. 1) Identification of barriers to iFOBT use and selection of intervention components, 2) pilot testing and 3) adjustment before large scale implementation.

Setting

The study was conducted in the Central Denmark Region, which is covered by 832 GPs working in 385 general practices. Each GP has approx. 1550 persons listed with their practice.¹⁵ GPs in Denmark own their clinic and act as gatekeepers to secondary care.

Developing the intervention

Initially, a research group consisting of primary care researchers, GPs and clinicians from secondary care conducted a COM-B analysis to identify determinants and possible interventions for GPs to start using the iFOBT. The identification of barriers was primarily based on clinical experience from general practice. The most important and feasible intervention components were selected based on the Normalisation Process Theory, local experience and literature reviews of continuous medical education (CME).¹⁶⁻¹⁹ The intervention model was pilot-tested among 10 GPs in seven GP practices from 1 March 2015–31 May 2015. The pilot period was evaluated both quantitatively by measuring the iFOBT requests and qualitatively by individual GP interviews. Finally, the intervention was adjusted before large scale implementation.

Results

Identification of barriers and selection of intervention components

Three major barriers were identified: 1) the GPs' capability to start using the test was generally limited by a lack of knowledge about the clinical indications and how to perform

the test, 2) their opportunity to start using the test was restricted by cumbersome test ordering procedures and lack of support from practice staff and 3) their motivation were restricted by competing tasks, lack of remuneration and uncertainty about other GPs' opinions. From this, three intervention components were developed: 1) A clinical guideline on the use of iFOBT in general practice. It defined the target population and listed indications and contraindications for iFOBT use. 2) A focused GP training course to improve knowledge on the iFOBT and familiarise GPs with the test kit and how to order the test. The course was developed as a 45 minute small-group interactive presentation with time for comments and discussion. 3) A test kit and an easy online ordering procedure. Furthermore, the Organisation of General Practitioners in the Central Denmark Region negotiated a remuneration fee for using the iFOBT and recommended its use.

Pilot testing

All GPs started using iFOBT during the pilot period and in total, 72 iFOBTs were requested. The interviews revealed that the GPs found the list of indications to be rigid and out of step with the clinical situation, and that the section "contraindications" were considered as unnecessary. Furthermore, the GP training course provided the GPs with the necessary knowledge and skills to use the iFOBT; the GPs reported that they felt motivated to use the iFOBT and confident on how to introduce the test in their clinics. Finally, many GPs found it difficult to find the iFOBT request on the website for ordering laboratory tests.

Adjusting the intervention

The guideline was revised in accordance with the findings of the pilot testing, and it was left to the individual GP's clinical judgement to decide when to use the iFOBT. The website for ordering iFOBT was modified to make the iFOBT request more easily found and to ensure that the workflow and the instructions for patients would be similar to those already in use.

Discussion

This article describes a rapid theory-based development of an intervention to facilitate quick uptake of a new laboratory test in general practice. The COM-B model linked the analysis

of barriers to specific intervention functions and facilitated a common understanding in the research group. We used a pilot study to confirm the importance of the intervention components as recommended in the guidelines for the development of complex interventions.¹⁴ The pilot study also provided us with crucial insights into unforeseen barriers, which probably would have led to project failure in a large scale study. We found that GPs were reluctant to use the iFOBT if they felt obliged to use a rigid general guideline instead of their own clinical judgement. We also found it important to build on existing routines when introducing a new test to facilitate quick uptake.¹⁶

We believe that the transparency of the process will allow others to interpret our findings and apply them in similar settings. Likewise, our results may help introduce other new tests in similar settings in the future.

ETHICAL APPROVAL

The study obtained ethical clearance from the Committee on Health Research Ethics in the Central Denmark Region (j.no. 142/2014).

ACKNOWLEDGEMENT

The authors would like to thank biomedical laboratory technician Erik Sloth Jørgensen who made the ordering system for iFOBT and Nete Hornung (head of the Department of Clinical Biochemistry at the Regional Hospital of Randers), who was in charge of analysing the iFOBTs in the pilot period. The authors would also like to thank Morten Bondo Christensen and Marie-Louise Heine Jensen, who set up the GP training course and assisted in the data collection. The Cancer in Practice unit in the Central Denmark Region financed the iFOBT kits and played a key role in conducting the pilot test. Søren Laurberg (professor and MD at Department of Surgery, Aarhus University Hospital), Berit Andersen (PhD and MD at Department of Public Health Programs, Regional Hospital of Randers,) and Frede Olesen (professor and MD at Research Unit for General Practice, Aarhus University) were part of the research group together with the authors of this article.

SOURCE OF FUNDING

The study was funded by the Cancer in Practice unit in the Central Denmark Region.

TRIAL REGISTRATION

This study was registered in the NCT Clinical Trial Registry (Clinicaltrials.gov) under NCT02308384 on November 26, 2014.

REFERENCES

- Hamilton W. Five misconceptions in cancer diagnosis. *Br J Gen Pract* 2009; 59: 441-445.
- Juul JS, Vedsted P. Uncharacteristic colorectal cancer symptoms and their value in general practice. *Ugeskr Laeger* 2012; 174: 710-713.
- Nielsen TN, Hansen RP, Vedsted P. Symptom presentation in cancer patients in general practice. *Ugeskr Laeger* 2010; 172: 2827-2831.
- McDonald PJ, Digby J, Innes C, Strachan JA, Carey FA, et al. Low faecal haemoglobin concentration potentially rules out significant colorectal disease. *Colorectal Dis* 2013; 15: 151-159.
- Kaul A, Shah A, Magill FH, Hawkins SA, Skaife P. Immunological faecal occult blood testing: A discriminatory test to identify colorectal cancer in symptomatic patients. *Int J Surg* 2013; 11: 329-331.
- Kok L, Elias SG, Witteman BJ, Goedhard JG, Muris JW, et al. Diagnostic accuracy of point-of-care fecal calprotectin and immunochemical occult blood tests for diagnosis of organic bowel disease in primary care: The cost-effectiveness of a decision rule for abdominal complaints in primary care (CEDAR) study. *Clin Chem* 2012; 58: 989-998.
- Mowat C, Digby J, Strachan JA, Wilson R, Carey FA, et al. Faecal haemoglobin and faecal calprotectin as indicators of bowel disease in patients presenting to primary care with bowel symptoms. *Gut* 2015.
- Parente F, Marino B, Ilardo A, Fracasso P, Zullo A, et al. A combination of faecal tests for the detection of colon cancer: a new strategy for an appropriate selection of referrals to colonoscopy? A prospective multicentre Italian study. *Eur J Gastroenterol Hepatol* 2012; 24: 1145-1152.
- Jellema P, van dW, Bruinvels DJ, Mallen CD, van Weyenberg SJ, et al. Value of symptoms and additional diagnostic tests for colorectal cancer in primary care: Systematic review and meta-analysis. *BMJ* 2010.
- Cubiella J, Salve M, Diaz-Ondina M, Vega P, Alves MT, et al. Diagnostic accuracy of faecal immunochemical test for colorectal cancer in symptomatic patients: comparison with NICE and SIGN referral criteria. *Colorectal Dis* 2014; 24: 273-282.
- Juul JS, Bro F, Hornung N, Andersen BS, Laurberg S, et al. Implementation of immunochemical faecal occult blood test in general practice: A study protocol using a cluster-randomised stepped-wedge design. *BMC Cancer* 2016.
- Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci* 2011; 6: 1-11.
- Thabane L, Ma J, Chu R, Cheng J, Ismaila A, et al. A tutorial on pilot studies: The what, why and how. *BMC Med Res Methodol* 2010; 10: 1-10.
- Moore GF, Audrey S, Barker M, Bond L, Bonell C, et al. Process evaluation of complex interventions: Medical research council guidance. *BMJ* 2015.
- Pedersen KM, Andersen JS, Sondergaard J. General practice and primary health care in Denmark. *J Am Board Fam Med* 2012; 25 1: S34-S38.
- May C, Finch T. Implementing, embedding and integrating practices: An outline of normalization process theory. *Sociology* 2009; 43: 535-554.
- Guldbrandt LM, Rasmussen TR, Rasmussen F, Vedsted

- P. Implementing direct access to low-dose computed tomography in general practice--method, adaption and outcome. PLoS One 2014.
18. Toftegaard BS, Bro F, Vedsted P. A geographical cluster randomised stepped wedge study of continuing medical education and cancer diagnosis in general practice. *Implement Sci* 2014; 9: 159.
19. Forsetlund L, Bjorndal A, Rashidian A, Jamtvedt G, O'Brien MA, et al. Continuing education meetings and workshops: Effects on professional practice and health care outcomes. *Cochrane Database Syst Rev* 2009.

ADDRESS FOR CORRESPONDENCE:

Jakob Søgaaard Juul, Research Unit for General Practice, Department of Public Health, Aarhus University Bartholins Alle 28000 Aarhus C, Denmark, Tel: +45 8716 8537; E-mail: j.juul@ph.au.dk

Submitted: November 28, 2016; Accepted: December 22, 2016; Published: December 29, 2016