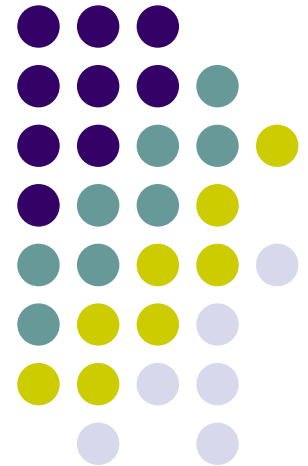
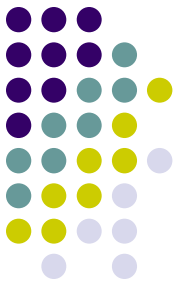


# Planning and conduct of theory based process evaluations alongside randomised trials of behaviour change interventions

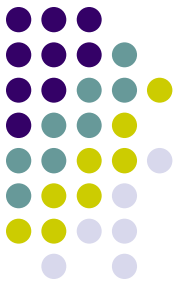


# Exploring value of theories in implementation research



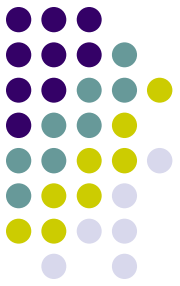
- *Validation studies* testing the applicability of theories about individual behaviour to professional behaviour.
- *Typology/ taxonomy studies* use specific theories as a framework to investigate factors associated with particular behaviours.
- *Theoretically based process studies* alongside rigorous evaluations to generate hypotheses about the effectiveness or otherwise of the strategy.
- *Rigorous evaluations of theoretically based interventions.*

# Theory based process evaluations



- Collect data on theoretical construct(s) alongside randomised trials to explore possible causal mechanisms

# Theory based process evaluations



## Experience to date

- Thrush trial
- DREAM trial
- DRAM trial
- GP prevention trial
- C-spine decision rule implementation trial
- CT decision rule implementation trial

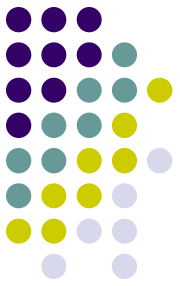
# Theory based process evaluations



## Issues

- Which theoretical constructs?
- What measures of theoretical constructs?
- When to measure theoretical constructs?
- Definition of behaviour?
- Identification of tracer behaviours?
- Sample size considerations for theoretical constructs?
- Analytical methods?

# Theory based process evaluations



- Which theoretical constructs?
  - TPB (+ others)
- What measures of theoretical constructs?
  - Direct measures (short)
  - Beliefs (long)
- When to measure theoretical constructs?
  - Post
  - Pre Post
- Identification of tracer behaviours?
  - Single
  - Multiple behaviours

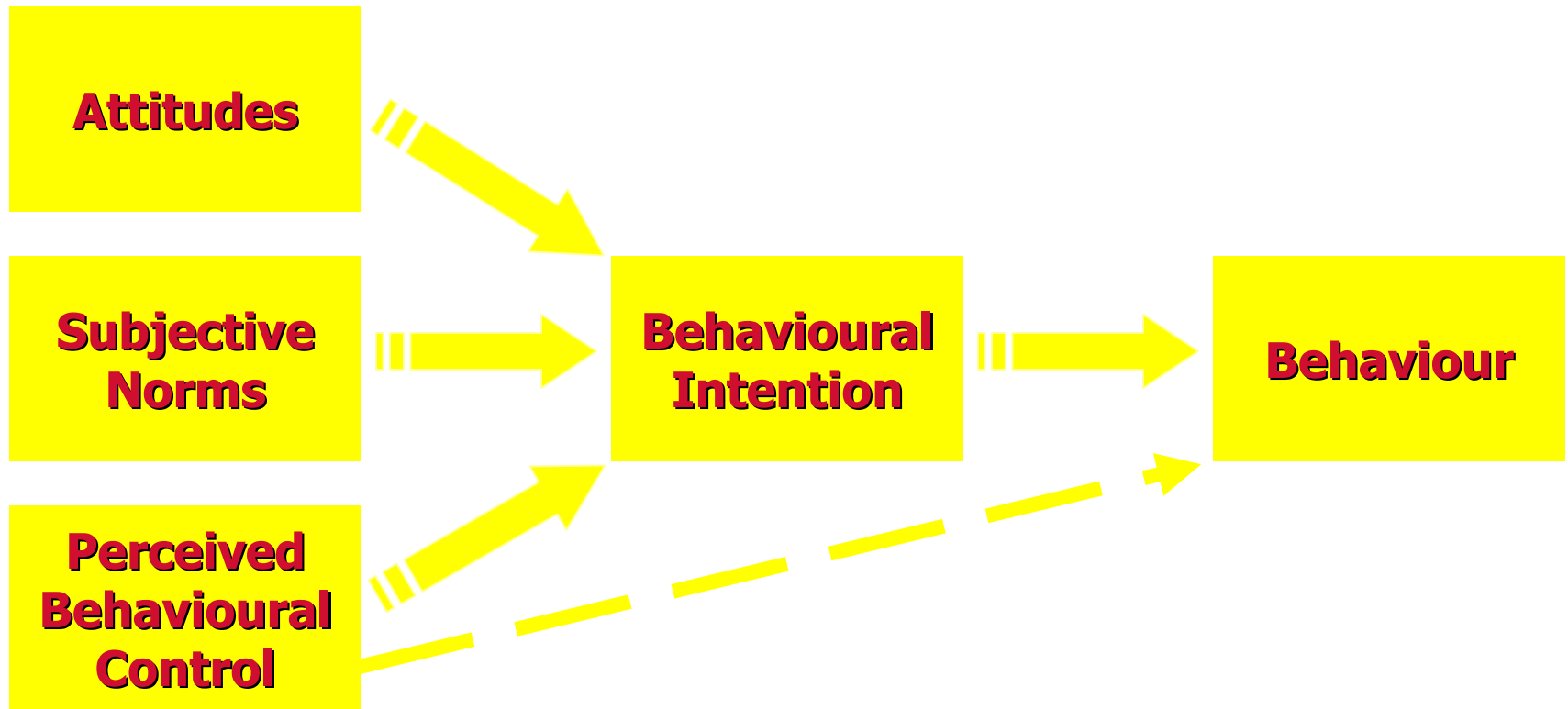
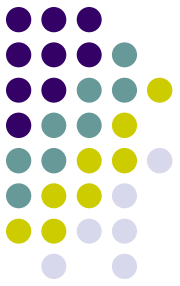
# Theory based process evaluations



## Experience to date

- Thrush trial (full TPB, pre post, 1 behaviour)
- DREAM trial (short TPB, post, 3 behaviours)
- DRAM trial (short TPB, post, 3 behaviours)
- GP prevention trial (full TPB, pre post, 2 behaviours)
- C-spine decision rule implementation trial (short TPB, pre post, 1 behaviour)
- CT decision rule implementation trial (short TPB, pre post, 1 behaviour)

# Theory of Planned Behaviour



Ajzen & Madden, (1986), *Journal of Experimental Social Psychology*, 22, 453

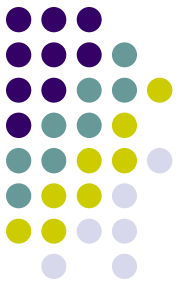


The Thrush  
Study!

# Design



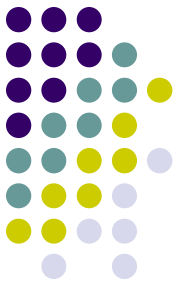
- 60 community pharmacies in North East of Scotland
- 2 x 2 factorial design
- Evidence based guidelines for over the counter treatment of vaginal candidiasis
- Pharmacies independently randomised to educational outreach vs control and CPD vs control
- Outcome assessed by simulated patients using standardised presentations



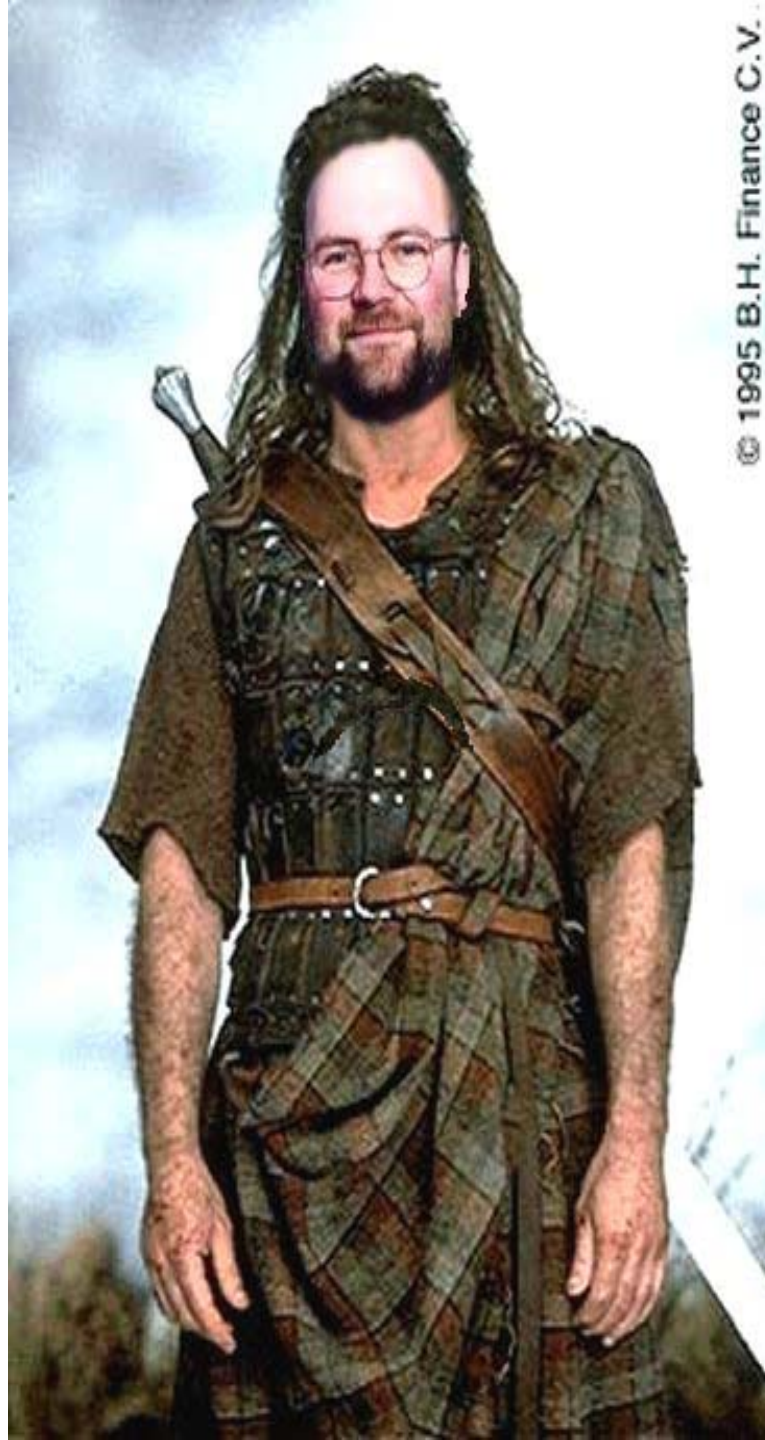
# Process evaluation

- Survey of pharmacists' knowledge about guideline recommendations and TPB survey to determine pharmacists' motivation to sell over the counter thrush treatments before and after intervention

# Results



- No significant differences observed for either intervention
- Process evaluation suggested that:
  - Baseline knowledge was high
  - Pharmacists were highly motivated to sell OTC treatments
  - Interventions may have been largely ineffective because they targeting knowledge and motivation
- Led to considerable discussion within project team about barriers and facilitators in community pharmacy setting influencing intention - behaviour gap.

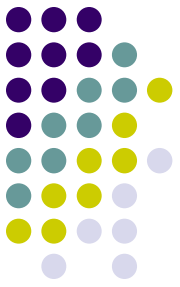


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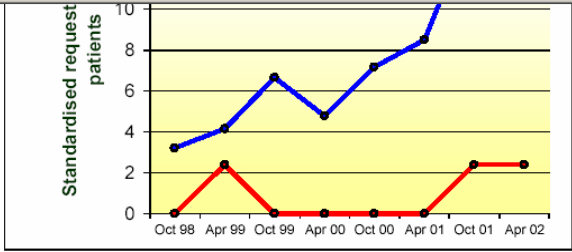
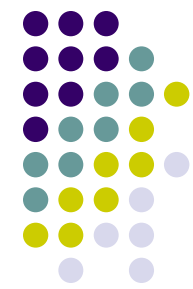


Man in  
need of a  
DRAM  
(study)

# Design



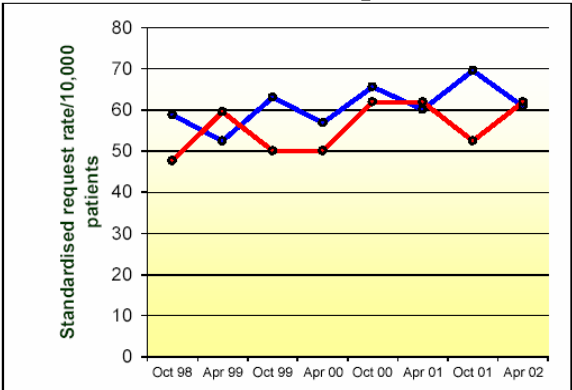
- ~90 general practices in North East of Scotland
- 4 arm trial
- Practices randomised to control, feedback, educational messages on test reports, feedback and educational messages
- Main outcome number of tests ordered from laboratory



**CA-125 should not however be used to screen, diagnose or exclude malignancy.** It can also be found to be raised in many other malignancies and benign conditions, notably gastrointestinal disorders. False positive and false negative results can therefore lead to unnecessary further investigation or false reassurance.

## Follicle Stimulating Hormone

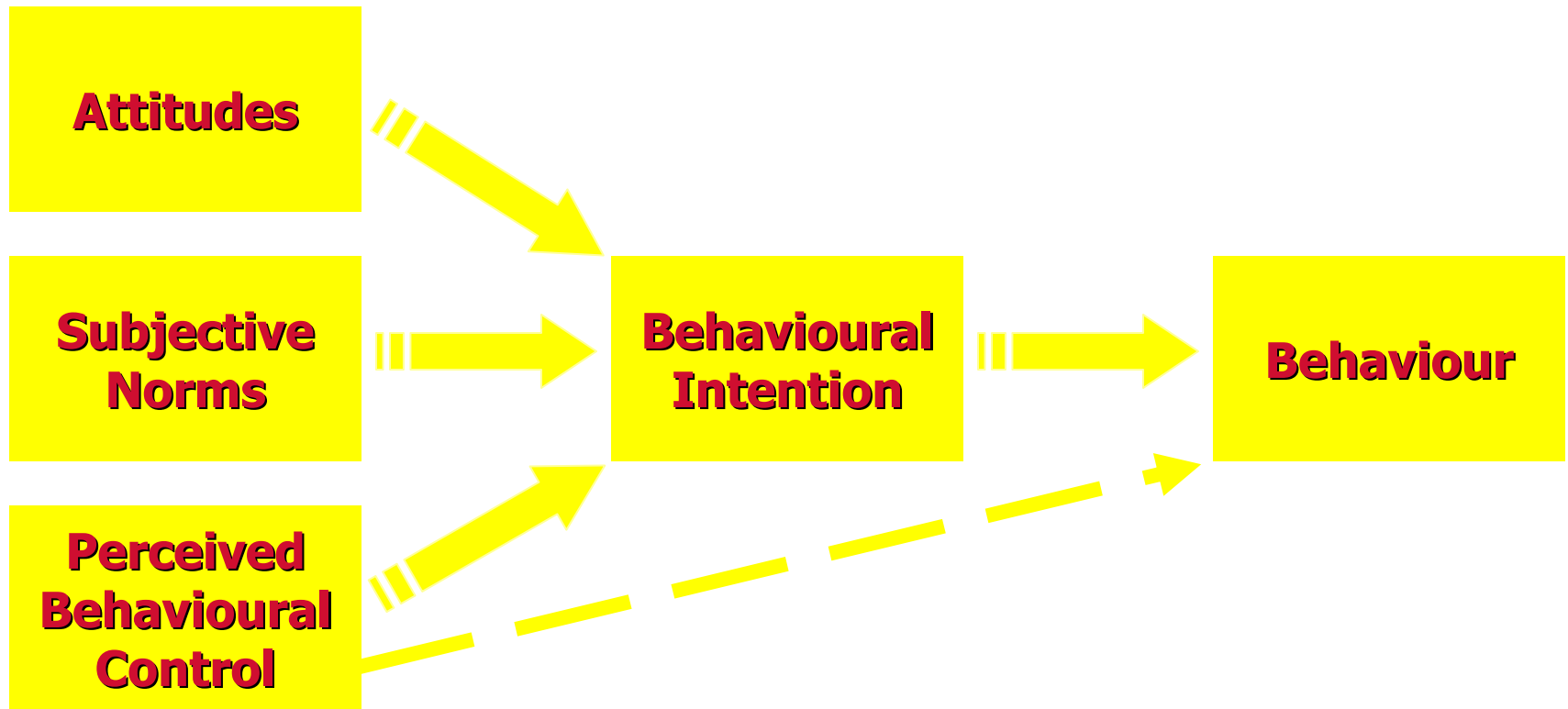
Grampian Average		60.7
Your Practice		61.9



Follicle Stimulating Hormone (FSH) is released by the pituitary gland and acts to stimulate sex hormone production and reproductive processes. **In general, FSH testing is of limited value in the assessment of menopausal status in women over 40 years of age, and so should not be requested for this purpose.** Menopausal/Peri-menopausal status is best confirmed retrospectively based on clinical symptoms, signs and frequency or absence of menstruation. Biochemical measurement adds little to this classification, and may mislead.

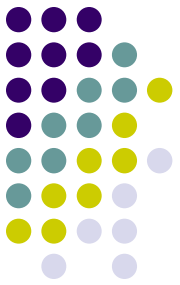
**\*Further Reading: Lindblom A, Liljegren A. Tumour markers in malignancies. BMJ 2000; 320: 424-427**

# Theory of Planned Behaviour



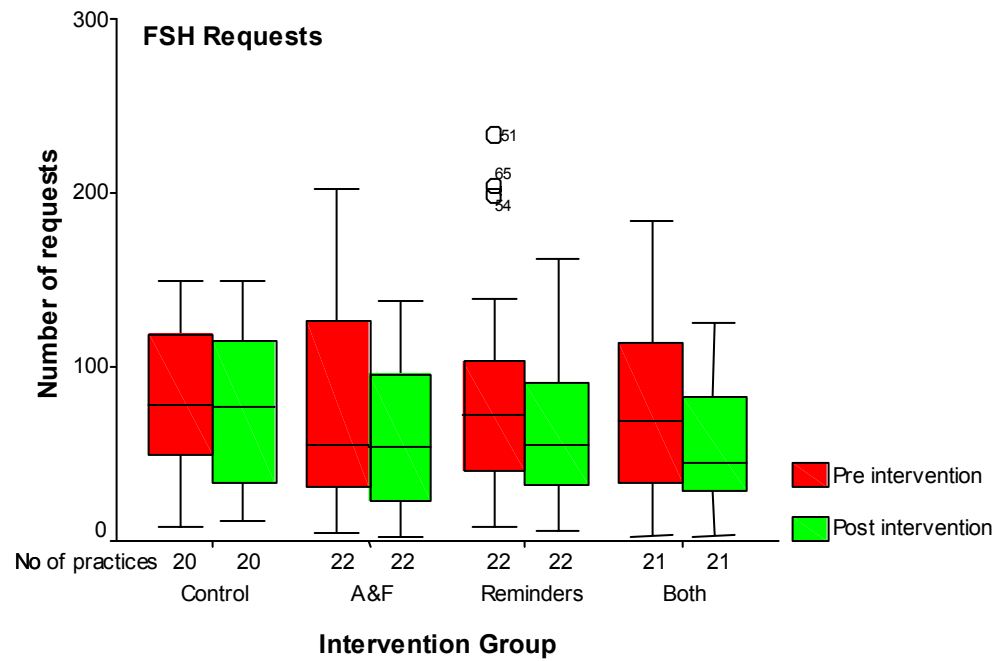
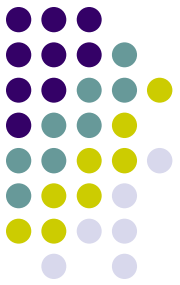
Ajzen & Madden, (1986), *Journal of Experimental Social Psychology*, 22, 453

# Results

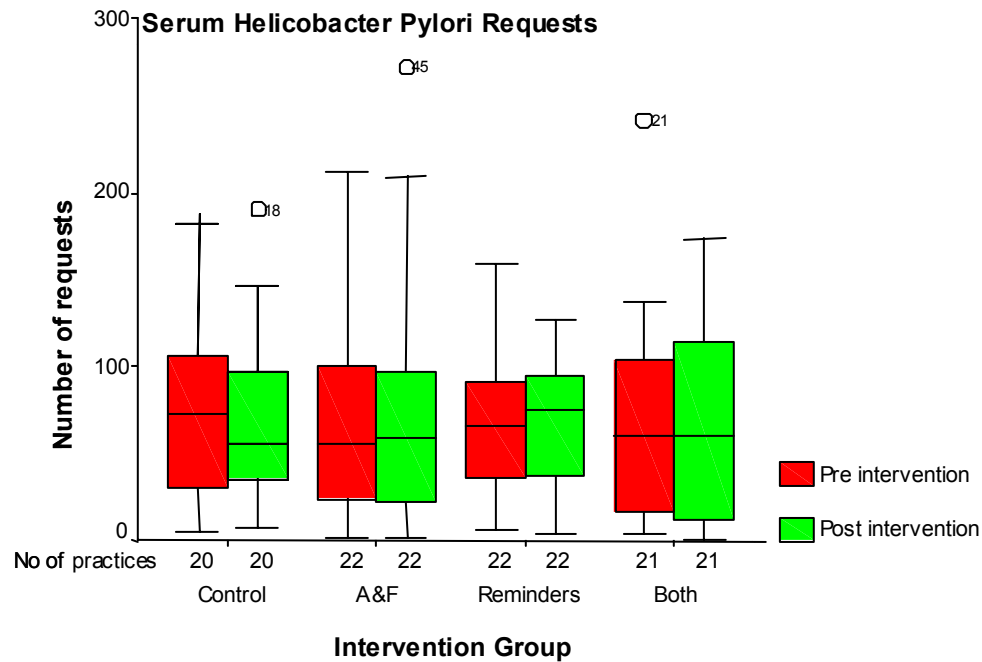
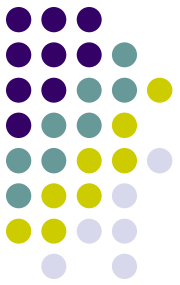


	Feedback	Educational messages	Feedback and messages
Number of tests with positive direction of effect	8/9	6/9	9/9
Median odds ratio (range)	0.84 (0.51 – 1.07)	0.88 (0.41 – 1.01)	0.79 (0.46 – 0.89)
Number of tests with statistically significant results	3/9	3/9	6/9

# Results - FSH



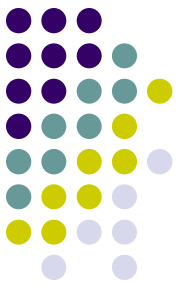
# Results – Helicobacter pylori





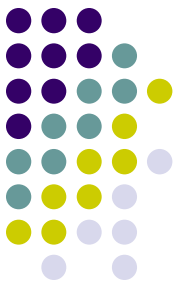
# Results - FSH

	Intention (1-7)	Attitudes (1-7)	Social norms (1-7)	PBC (1-7)
Control	4.3	4.2	4.2	2.0
Feedback only	5.6	5.2	4.9	1.5
Educational messages	6.0	5.5	5.2	1.5
Feedback and messages	6.0	5.7	5.2	1.5



# Results - Helicobacter

	Intention (1-7)	Attitudes (1-7)	Social norms (1-7)	PBC (1-7)
Control	6.3	7.0	6.0	2.2
Feedback only	7.0	7.0	6.0	2.2
Educational messages	7.0	7.0	6.2	1.2
Feedback and messages	7.0	7.0	6.3	2.0



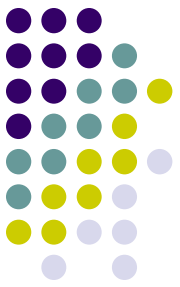
# Results

- Possible causal mechanism FSH – interventions enhanced attitudes and social norms resulting in improved intention and behaviour change
- Possible causal mechanism Helicobacter – high baseline attitudes, social norms and intentions ?psychological ceiling effect

# Summary



- Theory based process evaluations appear to be helpful in understanding potential causal mechanisms within trials



# Outstanding issues

- Which theoretical constructs?
  - TPB (+ others)
- What measures of theoretical constructs?
  - Direct measures (short)
  - Beliefs (long)
- When to measure theoretical constructs?
  - Post
  - Pre Post
- Identification of tracer behaviours?
  - Single
  - Multiple behaviours