Evidence Table

Clinical Area: Immunochemical FOBT

Study Type: Randomized controlled trial.

Outcomes
- **Primary**: Compliance with testing.
- **Secondary**: Proportion of positive tests.

Design
- **Number of subjects**: N=3,358. n=2419 immunochemical FOBT, iFOBT (Inform, Enterix); n=939 guaiac FOBT, gFOBT (Hemoccult II).
- **Description of study population**: Residents of a rural area of Australia.
- **Inclusion criteria**: Patients of participating GPs; age 50-74 years old
- **Exclusion criteria**: None mentioned.
- **Intervention**: Participants were mailed a letter signed by their GP, an information pamphlet on CRC screening and an FOBT kit. Reminders were sent to non-responders eight weeks after the initial mailing. Instructions for the gFOBT included sampling three consecutive evacuations and abstaining from certain foods and medications before testing. Completed guaiac test cards needed to be taken to the local hospital for analysis. The iFOBT involved sampling two stools and did not require any dietary restrictions. Completed test cards were sent through the mail. Patients who tested positive were referred to their GP for follow-up.
- **Source of outcome data**: FOBT results.

Validity
- **Blinding?** Assume that FOBT analysis was blinded.
- **Appropriate randomization procedures?** Did not randomize by patient or GP. Instead, combined the largest and smallest practice, and the two middle practices and flipped a coin to see which patients should receive which test. This may have resulted in inadequate randomization, and did result in uneven group size (72% of the patients were in one group).
- **Appropriate comparison intervention?** Yes.
- **Treatment/control groups comparable at baseline?** The authors only presented information about age and gender; the groups differed in terms of age distribution.
- **Other than intervention, was care/follow-up similar in each group?** Yes.
- **Sufficient statistical power?** Not reported.
- **Intention to treat analysis?** Excluded 503 individuals post-randomization from the analysis because they received both test kits.
• **Industry funding?** Primarily funded by government. Received some funding from Enterix which provided discounted iFOBT kits and analysis. Stated that Enterix had no role in data analysis or interpretation.

• **Conclusions regarding validity of methods:**
This study used an unconventional design and their method of randomization may have introduced bias. The methodology did result in highly skewed group size. Some bias may have been introduced by funding from Enterix, the makers of Inform.

**Results**

**Primary outcome**

<table>
<thead>
<tr>
<th></th>
<th>Immunochemical (n=2419)</th>
<th>Guaiac (n=939)</th>
<th>Adj OR (^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Returned samples</td>
<td>38.7%</td>
<td>30.2%</td>
<td>1.88 (1.59-2.22)</td>
</tr>
</tbody>
</table>

\(^1\) Adjusted for age and gender.

**Secondary outcome**

<table>
<thead>
<tr>
<th></th>
<th>Immunochemical</th>
<th>Guaiac</th>
</tr>
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<tbody>
<tr>
<td>Prevalence of positive tests</td>
<td>9.5%</td>
<td>3.9%</td>
</tr>
</tbody>
</table>

**Authors’ Conclusions**

“An immunochemical FOBT enhanced participation. Higher positivity rates for this kit did not translate into higher false-positive rates, and both test types resulted in a high yield of neoplasia.”

**Reviewer’s Conclusions**

This study found a higher participation rate (defined as returning kits for analysis) among the group who received immunochemical tests compared to the group who received guaiac tests. The study had unconventional randomization procedures which may have introduced bias. The study was conducted in a rural area of Australia and results may not be generalized to the GHC population.