

Does a positive MCED screening result cause psychological harm? A longitudinal observational study nested in the NHS-Galleri trial

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Background

MCED tests are being evaluated for screening asymptomatic people. It is essential to understand the potential psychological harm associated with a positive result. Psychological harm in screening is frequently operationalised as anxiety, distress or decreased quality of life.¹

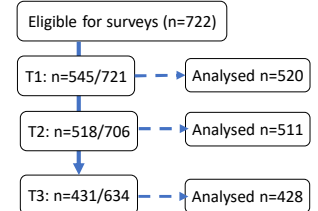


We assessed psychological outcomes following a positive MCED test result (i.e. a cancer signal was detected) among participants in the NHS-Galleri trial (NCT05611632), a large RCT in England designed to assess the clinical utility of the blood-based Galleri® test (GRAIL, Inc., Menlo Park, CA, USA).²

Methods

All participants with a positive MCED test result following their first blood test, were sent three questionnaires:

- T1: immediately after receiving their result
- T2: at 6-months, after diagnostic testing
- T3: 14-16 months after T1 (after the second Galleri® test result for those without cancer)



Outcomes included Anxiety (STAI-6)³, social, emotional and physical consequences of screening (PCQ)⁴, and single items assessing concern and reassurance.⁵ Items assessing concern about family and finances were added following PPI input.

Results

Figure 1: Anxiety scores (STAI) at T1 and T2 by self-reported diagnosis

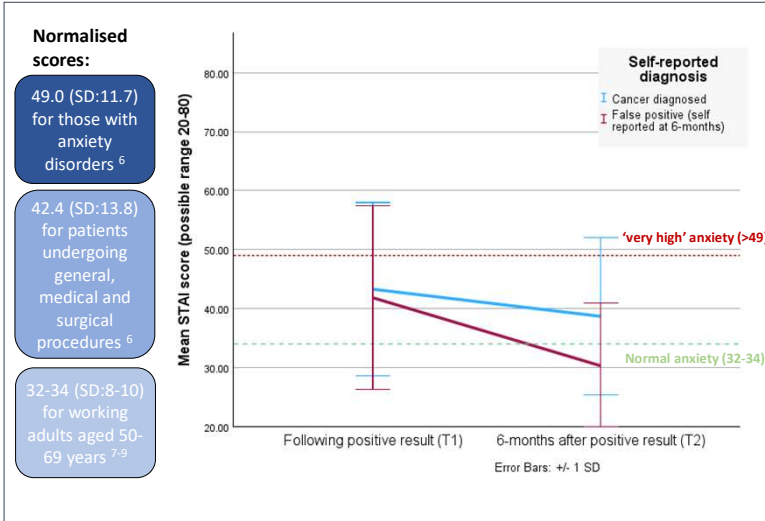


Figure 2: Odds ratios (with 95% CI) for 'Very High' anxiety at T1 (adjusted)

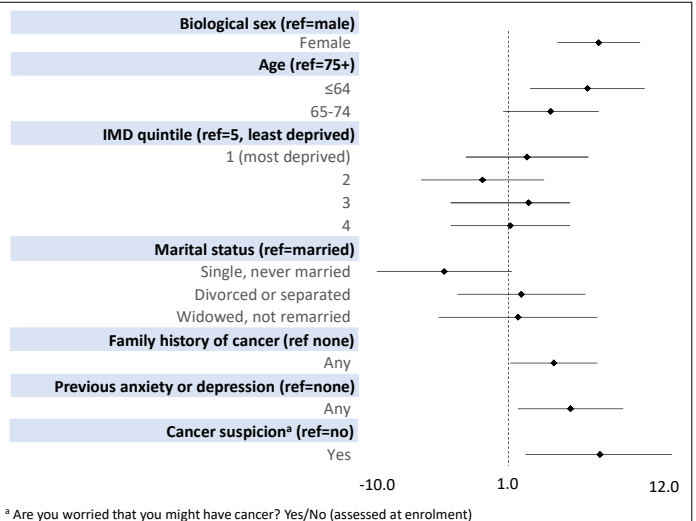


Table 1: Descriptives at each time point, reported by cancer diagnosis at 6-months and by result group/cancer diagnosis at 14-16 months (unadjusted)

	T1	T2	T3 ^b			
	T1 all (n=520)	False positive ^a (n=186)	Cancer diagnosed ^a (n=284)	Positive result at 12-month test (n=81)	Negative result at 12-month test (n=121)	Cancer diagnosed ^c (n=219)
	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)
Anxiety (STAI) (range 20-80)	43.37 (15.63)	31.38 (11.32)	38.43 (13.31)	34.38 (12.36)	32.05 (12.36)	33.59 (11.53)
PCQ-Global (range 0-36)	8.85 (7.55)	6.01 (7.08)	11.60 (8.04)	5.64 (5.96)	5.84 (6.87)	9.37 (7.88)
	% (CI)	% (CI)	% (CI)	% (CI)	% (CI)	% (CI)
Very high anxiety (over 49)	35.4 (31.1-39.9)	7.0 (3.8-12.2)	23.4 (18.3-29.4)	12.1 (5.7-23.2)	10.8 (6.0-18.4)	10.3 (6.6-15.6)
High concern about result	51.6 (47.2-55.8)	16.1 (11.4-22.2)	Not assessed	14.8 (8.5-24.3)	5.0 (2.1-10.8)	Not assessed
Low reassurance about result	31.5 (27.6-35.7)	16.9 (12.0-23.1)	Not assessed	35.0 (24.4-45.9)	30.5 (22.9-39.3)	Not assessed
High concern about finances	13.9 (11.1-17.1)	17.3 (12.4-23.6)	21.2 (16.7-26.4)	13.9 (7.8-23.4)	14.5 (9.2-22.1)	18.7 (14.0-24.5)
High concern about family	55.5 (51.2-59.7)	32.6 (26.1-39.8)	65.8 (60.0-71.2)	35.1 (25.3-46.2)	25.0 (18.0-33.6)	1.4 (44.7-58.1)

^a Self-reported within the T2 survey, not reported for those who did not answer this question (n=12) or were still awaiting resolution (n=29); ^b Not reported for those who did not attend their second test; ^c Within 12-months of first blood test.

Conclusions

- Consistent with studies of anxiety and broader psychological consequences following single-site cancer screening, the negative psychological impact was highest immediately after receipt of the initial positive result. Reassuringly, few people remained highly anxious 6 months later.
- Following a second positive MCED test, fewer people reported raised anxiety compared with after the first test, and for those who did, it was not as high. Low reassurance persisted after a second positive result.
- Females, younger age-groups and those with a previous history of cancer or experience of anxiety/depression are most at risk.
- Communication around the meaning of results will be an important way to minimise psychological impact.

References

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