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**Evaluation of a breast cancer awareness DVD intervention**

**Study Protocol version 1.2**

Proposed research governance sponsor: Homerton University Hospital NHS Foundation Trust London

**Chief investigator**

I accept ultimate responsibility for the contents of this protocol.

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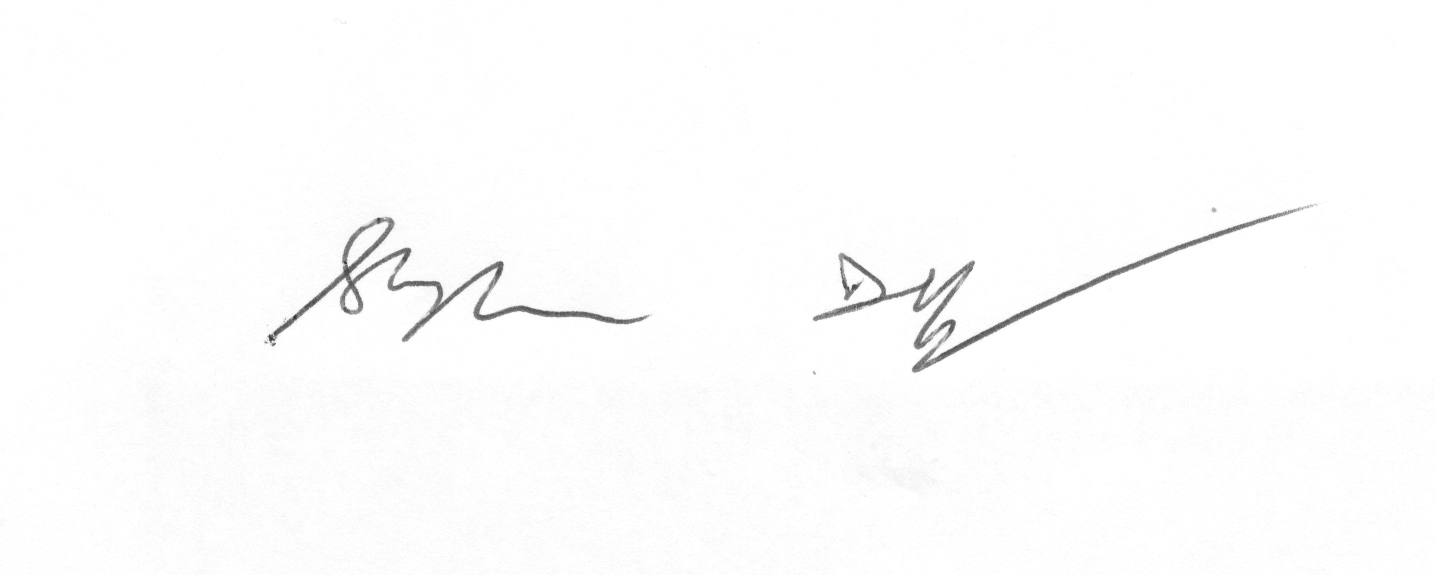
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1. **Title**

Evaluation of a breast cancer awareness DVD intervention

1. **Summary**

Researchers at Homerton Hospital noticed that while black women are less likely to develop breast cancer than their white counterparts, when they are diagnosed with breast cancer it tends to be at a younger age, typically before the age of entry into the NHS Breast Screening Programme. Black women also tend to be diagnosed with the more severe and aggressive types of breast cancer. Evidence suggests for various social and cultural reasons Black women are less breast aware and less likely to seek help from medical professionals. In response to these issues Homerton Hospital commissioned a six-minute information film ([www.gacomms.com/clients/breast-cancer](https://web.nhs.net/owa/redir.aspx?C=aa26bc9105134477817fcc15a00d0307&URL=http%3a%2f%2fwww.gacomms.com%2fclients%2fbreast-cancer)).

There is a clear need to evaluate the effectiveness of the DVD in raising awareness of breast cancer, encouraging early presentation and thereby promoting improvements in the detection of and prognosis for breast cancer in black patients. This study will pilot the distribution of the DVD amongst black women aged 25-50 in two GP practices within NHS East London and the City (with a further two practices recruited to serve as a control). A mixture of quantitative (analysis of consultation and referral rates) and qualitative (interviews with practice nurses and patient focus groups) methods will be used to evaluate the DVD’s impact. The findings from this study will inform the design of a full randomised trial evaluation.

1. **Background and Rationale**

NHS East London and the City has a high proportion of both younger people (with only 15% aged over 55, as opposed to 27% nationally) and Black and Black British residents (21% of Hackney residents, as opposed to an average of 4% in the City of London as a whole). NHS East London and the City also has a corresponding higher than average black breast cancer population. Nationally non-white ethnic groups make up 5% of mastectomy patients (National Mastectomy and Breast Reconstruction Audit), but in London this figure rises to 22%.

Data from Homerton University Hospital has found that the mean age of presentation for breast cancer in black women is some 20 years earlier than their white counterparts (Siam and Mahir, 2004). Data from Birmingham similarly found black women were presenting with breast cancer on at least 10 years earlier than their white counterparts (Abbott et al, 2011). Black women also present with adverse prognostic factors that have major clinical implications (Bowen et al 2008) and survival rates are lower in black women than in other groups (National Cancer Information Network 2009).

Cancer awareness is lower amongst ethnic minorities (Robb et al 2009) with considerable variations in awareness between ethnic groups (Waller et al. 2009). These trends exacerbate recognised lower utilisation of hospital and cancer screening services amongst these groups (Quan et al 2006). Results from the USA indicate black breast cancer patients tend to have delayed diagnoses and less screening coverage (Rahman et al, 2003; Goran et al, 2006). In the UK, lower socioeconomic status is associated with poorer breast cancer survival, and this is partly explained by later stage at presentation (Kaffashian et al, 2003).

A complex mix of social, cultural, economic and political factors shapes the way community members perceive and access healthcare services (Dyck 2006; Ahmad and Bradby 2007,Dyck and Dossa 2007). Social factors also impact on breast awareness and help-seeking behaviour among black and ethnic minority women (Thomas et al 2005), suggesting a need for culturally sensitive, community-based interventions to raise awareness and encourage early presentation (Waller et al 2009).

In response to these challenges, Homerton Hospital have produced a six minute DVD ([www.gacomms.com/clients/breast-cancer](https://web.nhs.net/owa/redir.aspx?C=aa26bc9105134477817fcc15a00d0307&URL=http%3a%2f%2fwww.gacomms.com%2fclients%2fbreast-cancer)). While information DVDs have been used in various settings to convey public health information (see for example the Personal Health Budgets film produced by the NHS at <http://www.personalhealthbudgets.dh.gov.uk/About/Stories/>), but such interventions are rarely, if ever, evaluated. Consequently there is no evidence based as to whether or not DVDs are an effective mechanism for communicating health information. This new DVD produced by Homerton hospital provides a timely opportunity to assess the effectiveness of this mode of interventions for targeting hard-to-reach groups.

1. **Objectives and purpose**

The aims of this study are to:

(i) Distribute the DVD to black women aged 25-50 in five GP practices within NHS East London and the City (with a further five practices recruited to serve as a control).

(ii) Obtain estimates of its impact on consultation and referral rates in each practice, and carry out qualitative research (focus groups with patients from the target population and interviews with practice nurses) on its acceptability and communicative function.

1. **Experimental design and methods**

*Sampling*

NHS East London and the City includes around 48 GP practices. While there is some demographic variation between these practices in terms of the age, ethnicity and socio-economic group, all practices show a consistently higher proportion of black patients (around 30% of the whole as opposed to 45 in greater London). The total number of women aged 25-50 ranges from around 200 to 3000 per practice. The maximum age in our study reflects the age of entry into the national breast cancer screening programme (50). The minimum age has been selected as the earliest cases at Homerton include women as young as 25. In terms of raising breast awareness it is also desirable to target women at a younger age before they are likely to develop symptoms. Our estimated target population is therefore around 20160 (48 (no. of practices) x1400 (median estimated no. of women aged 25-50) x .3 (proportion of population who are black)).

With the assistance of members of NHS East London and the City will recruit 10 practices in the City and Hackney area (with an estimated black female population aged 25-50 of 1680). 5 practices will be selected at random from these 10. Using practice lists we will aim to post the DVD to all black women aged 25-50 registered at these 5 practices (excluding those who already have a previous diagnosis of breast cancer). The 5 practices who have not received the DVD will serve as control practices. This will allow us to evaluate the impact of the DVD. (Control practices will receive copies of the DVD to distribute once the study is complete for equity reasons.) We have included in our costing provision for compensating participating practices for the time costs involved in participating in the study.

*Quantitative Evaluation*

Using the EMIS database we will analyse data on consultations regarding breast symptoms and referral rates for breast symptoms, by age and ethnicity for all participating GP practices for 6 months after the intervention and the corresponding 6 months from the previous year before the intervention. We will augment this with a manual audit of a random subset of GP consultations. Using this data we will evaluate the impact of the DVD on consultation and referral rates. Ten practices would be expected to contain around 4200 black women in our age range of interest. This would confer 80% power to detect a change in rate of consultations from 14 per thousand per year to 26 per thousand per year.

Data will be analysed by poisson regression. In terms of data quality from the EMIS searches, we shall draw up a practice search protocol for a series of codes related to breast symptoms (for example including codes for mastalgia, and mastodynia as well as ‘breast pain’, and excluding consultations with codes specific to breast feeding problems. Ethnicity data in general practices in NE London is 92% complete (http://www.icms.qmul.ac.uk/chs/Docs/63543.pdf).

*Qualitative Evaluation*

In addition to the quantitative analysis, recent studies have recognised the value of incorporating more qualitative and community-focused methods in the development of interventions to raise cancer awareness within ethnic minority communities (Nunn et al 2009; Eilbert et al 2009; Lyon et al 2009). Qualitative research methods provide a way of systematically exploring, recording and analysing the insights and experiences of user groups, and can play a key role in capturing aspects of the impact of community-based healthcare interventions (such as increases in social capital) which are hard to assess quantitatively. Previous research on healthcare within multicultural societies suggests that a complex mix of social, cultural, economic, political factors shapes the way community members perceive and access healthcare services (Dyck 2006; Dyck and Dossa 2007). Qualitative approaches have proven effective in identifying these factors and how they impact on levels of breast awareness and help-seeking behaviour among black and ethnic minority women (Thomas et al 2005). Interviews and focus groups can offer insights into how ethnic differences in health outcomes are indicative of wider social and economic inequalities and highlight the diversity of experience within ethnic groups (Ahmad and Bradby 2007). Assessments undertaken elsewhere suggest a strong potential for community–focused interventions to improve cancer awareness (Lyon et al 2009) and the uptake of screening services (Eilbert et al 2009), but none of these studies has focused specifically on black women in the UK. Equally, while interviews and focus groups have been used to inform the design of cancer screening interventions (Nunn et al 2009) they have not (to our knowledge) been used in the evaluation of such measures. In this study focus group discussions (Longhurst 2003) with patients from participating practices are used to gain insight into their levels of cancer awareness and to gage their response to the DVD.

Within each of the 10 participating GP practices we will:

1)    Conduct a focus group with members of the black female patient population, aged 25-50, around 1-2 months following the distribution of the DVD (to allow patients sufficient time to view the DVD but not so much time they will have forgotten receiving it). We will aim to recruit 8-10 participants from each practice. Recruitment will be facilitated by staff at the participating practices, in addition to advertising at those practices. Focus groups will explore:

a.   Levels of breast cancer awareness amongst the group, using the breast cancer component of the Cancer Awareness Measure (Stubbings *et al* 2009) as the basis for developing discussion.

b.   If one of the practices where the DVD had been distributed, how many women in the group had received and watched the DVD and factors that influenced the decision to watch/not watch (thus exploring levels of compliance).

c.   Responses to the DVD (including a screening of the DVD for those who had not watched it).

2)   Interview a key healthcare worker in each practice (ideally one of those most closely involved with breast symptoms and breast awareness e.g. a practice nurse) for their perspective on general levels of breast awareness within their practice community, existing alternative interventions, and the effectiveness of the DVD. As health worker opinions are not the key focus of the project (but rather a means of gaining a more complete picture of the practice community and acknowledging the practice perspective/voice), and a larger sample has cost and recruitment concerns, it had been decided one worker per practice should be sufficient.

Focus groups and interviews will be recorded, transcribed, coded and analysed thematically (Cope 2003) to identify key factors shaping the response to the DVD and its likely effect in terms of breast awareness and help-seeking behaviour. Codes are used to systematically identify issues and themes arising during the interview. There are two broad stages to coding. Firstly, open or axial coding identifies key issues and recurring themes that emerge during the interview, often using the participant's own language. For example, if women mention childcare preventing them from seeing the GP sooner, childcare would become a code. Second level coding then extrapolates from these trends to link them to broader issues, such as the pressure of family commitments. The trends and issues emerging from the transcripts can then be compared to look for emerging themes, such as the impact of family commitments on access to health services. Coding provides a rigorous and systematic way of analysing qualitative data, providing a list of emerging themes and issues that can be usefully compared and contrasted with the trends emerging from the quantitative study data.

Finally, we will organise an action research workshop (Breitbart 2003) with 30 selected participants to evaluate the DVD, explore alternative interventions and generate ideas for future intervention strategies. The workshop will include 15 lay representatives drawn from the local community (ideally Black women, aged 25-50, women who fit the DVDs target audience and representatives of local community groups) and 15 representatives from Homerton Hospital (2), GPs/practice nurses (6), NHS East London and the City (2), local healthcare charities (2) and academics in the field of cancer awareness (3). Action research workshops are designed as non-hierarchical collaborative exercises where stakeholders meet to exchange ideas and develop strategies to address shared areas of concern (such as breast cancer awareness). The workshop will be used generate recommendations for the future use/distribution of the DVD, other areas where community-targeted DVD could be used as a social marketing resource for public health and alternative strategies for community-based healthcare interventions.

1. **Project timetable and milestones**

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| **October- November 2013** | Recruitment of general practices and distribution of DVD |
| **October –November 2013** | Recruitment of focus groups and interviewees |
| **November- December 2013** | Carry out focus group work and interviews |
| **January-April 2014** | Analyse focus group information, interview data |
| **May-July 2014** | Extract 6 month general practice consultation and referral data |
| **August-December 2014** | Extract 12 month quantitative data. Compare qualitative and quantitative results. Report results. |

1. **Risks and Ethical considerations**

The main risks are that the DVD is not well received or understood by the target population, or that it creates feelings of anxiety amongst participants. To address these concerns the DVD has been previewed and evaluated through four focus group discussions run by City and Hackney PCT (CHPCT, now NHS East London and the City) with young black women, older black women, a mixed group and a group of women who have previously had cancer. Feedback from these groups has been used to revise the DVD (funded by CHPCT), replacing a scene showing a doctor checking a woman’s breast (which made some women uncomfortable) with a scene showing a black woman checking herself (women wanted more information on self-examination). The focus groups also generated clear evidence of support for the DVD.

With respect to equipoise, it is proposed that while the study design proposes to only distribute the DVD to members of the target population in two of the four participating practices, with two serving as control, once the study is complete copies of the DVD will also be distributed in the control practices.

*Consent for focus groups and interviews*

All participants will be informed about the study's purpose, objectives and what their participation entails, be assured that their choice to participate or not has no implications for their healthcare provision and that they can withdraw their participation at any time.

*Confidentiality*

Minimal personal data (name and contact details) we be collected by the qualitative research team for the purposes of organising focus group or interview meetings and for providing feedback to participants on the study findings if requested. This data will be stored securely in a separate location from the interview and focus group recordings and transcripts, and destroyed once the study is complete. Interviews and focus groups will be anonymised prior to transcription. No personally identifiable information will be included in the interview and focus groups transcripts or subsequent research analysis and publications.

*Conflict of interest*

As the research team leads for this project (Duffy and Greenhough) are both fulltime

academic researchers with no healthcare role, and whom were not involved in producing the DVD, there are no conflicts of interest.

1. **Benefits of the study**

This study has potential to deliver an effective intervention to improve stage of breast cancer in a traditionally ‘hard-to-reach’ population. This type of short, snappy DVD intervention is a departure from routine health information dissemination.  It is just six minutes and is available with or without subtitles so could be shown in public places without volume as well as at home or other settings.

In summary, the benefits will be:

1. Improved early presentation of breast cancer amongst Black women aged 25-50 in NHS East London & the City.
2. Quantitative and qualitative evidence for and against the effectiveness of the DVD as a method of implementing community targeted healthcare interventions.
3. Preliminary estimates of effect on consultations and referrals which will be used to design a full randomised trial evaluation.
4. **Direct access to data and documents**

The investigators and their institution will allow study-related monitoring, audits and review by authorised governance and regulatory bodies, and all direct access to source data and documents

1. **Resources and costs**

This study is funded by Barts and the London Charity. There are no insurance/indemnity issues.

1. **Adverse events and side effects**

Since no clinical intervention is taking place, no adverse events or side effects are anticipated.

1. **Committees**

The PI will convene a steering committee of three independent scientists and will report to this committee at three-monthly intervals on the progress and conduct of the study

1. **Administration**

Investigators will adhere to all current regulations concerning research governance. See also 13 above.

1. **Dissemination of results**

Results will be published in peer-reviewed journals. Also, a summary of research findings will be produced for participating GP practices, Hackney and the City Public Health Directorate and for lay participants if requested.

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