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Does access to an information-based, breast cancer specific website help to reduce distress in young women with breast cancer? Results from a randomised trial.

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Abstract

To assess the effectiveness of a purpose-built information-based website to reduce distress among young women with breast cancer. 337 participants (Intervention Group (IG) n=202; Usual Care Group (UCG) n=177) returned the completed baseline questionnaires (T1). Details regarding accessing the website were provided to IG participants. Follow-up questionnaires were completed: i) three months (T2), and ii) six months after baseline (T3). Outcomes included anxiety and depression (primary outcomes), quality of life (QoL) and unmet information needs. 70% of the IG accessed the website, typically only once (median: 1, range 1-15), spending a median of 19 minutes (range: 1-315) on the site. Mean levels of anxiety and depression did not differ between the two groups at T1, T2 or T3. While improvement in total QoL was greater in the IG than UCG between T1 and T2, QoL scores did not differ between groups at T3. The number of unmet needs did not differ between the two groups at T3. The intervention was not effective in reducing anxiety, depression in this group of women. As a high number of unmet needs were identified, other strategies for addressing these needs of young women with breast cancer are needed.

Key words: Breast cancer, internet based resource, randomised trial, intervention, distress, quality of life

Introduction

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Although breast cancer is generally a disease of older women, around 25% of women diagnosed with this disease will be under the age of 50(Australian Institute of Health and Welfare & Cancer Australia 2012). Younger women with breast cancer are at increased risk of psychological distress, and poorer quality of life than older women with this disease(Howard-Anderson, Ganz et al. 2012, Campbell-Enns and Woodgate 2015). Young women face a number of different challenges to older women including the impact of treatment on fertility, disruption to caregiving roles and employment(Thewes, Butow et al. 2004, Thewes, Meiser et al. 2005, Ruddy, Greaney et al. 2013). While treatment guidelines recommend that all cancer patients receive comprehensive information and support, many young women with breast cancer report information deficits and dissatisfaction in the information they receive(Charif, Bouhnik et al. 2015). Low satisfaction with information received has been associated with lower quality of life and greater distress in cancer patients(Davies, Kinman et al. 2008, Trudel, Leduc et al. 2014, Faller, Koch et al. 2016).

A significant proportion of young women with breast cancer experience moderate to high information and supportive care needs during and after their cancer treatment(Thewes, Meiser et al. 2005, Ruddy, Greaney et al. 2013, von Heymann-Horan, Dalton et al. 2013, Fiszer, Dolbeault et al. 2014, Charif, Bouhnik et al. 2015). As higher levels of unmet information and supportive care needs are associated with greater psychological distress(Dyson, Thompson et al. 2012, Hansen, Larsen et al. 2013, Faller, Koch et al. 2016, Willems, Bolman et al. 2016), identifying strategies to meet the information and support needs of young women with cancer may reduce distress in this population. Despite the availability of breast cancer-specific information and support services, many women with breast cancer are unaware of these services(McGarry, Ward et al. 2013).

The internet is a common source of health information for the general population and for cancer patients with a US study finding that the internet was the first source of health information for 68% of the population in 2012/13(Volkman, Luger et al. 2014) and a Canadian study finding 57% of cancer survivors sourced information about their disease from the internet(Shea-Budgell, Kostaras et al. 2014). Internet health resources, have been classified into three types: i) sites that provide access to a wide range of information, ii) sites that enable people to communicate with each

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other through chat groups, bulletin boards etc; and iii) interactive communication or coaching systems that involve users working through a set of learning modules or expert systems to assist with behaviour change(Baker, Hawkins et al. 2011, Leykin, Thekdi et al. 2012).

Evidence for the effectiveness of internet resources for reducing distress or unmet needs in cancer survivors is mixed, with several RCTs of information/education based interventions showing no effect on distress(Ryhänen, Rankinen et al. 2013, Ventura, Sawatzky et al. 2013), while other trials report positive effects of these types of interventions on seeking information and health care participation(Gustafson, Hawkins et al. 2001, Gustafson, Hawkins et al. 2008, Damholdt, Mehlsen et al. 2016). A systematic review of 36 studies examining the effectiveness of internet-based resources on psychological outcomes also found the evidence was mixed(Paul, Carey et al. 2013). This review included seven studies involving cancer patients with five studies examining the effectiveness of online support programs. The review concluded there was little evidence for the effectiveness of these programs in reducing cancer patients distress(Paul, Carey et al. 2013). A more recent review of 18 articles examining health professional moderated internet-based programs for women with breast cancer, concluded that these programs had some positive effects on symptom management and well-being, but their effect on quality of life was inconclusive(Zhu, Ebert et al. 2017). Baker et al(Baker, Hawkins et al. 2011) conducted a trial testing the effectiveness of three types of internet resources in improving information competence and quality of life: i) an information-based online resource, ii) an information and support online resource, and iii) an information, support and coaching online resource, with the control group having 'ad lib' internet access only. While the information and the information and support system were more effective than the control arm in improving women's information competence, access to a coaching function did not improve the resource's effectiveness(Baker, Hawkins et al. 2011).

As the information only system increased women's information competence relative to the control group(Baker, Hawkins et al. 2011), providing access to an information-based internet resource may help reduce unmet information needs and improve psychological functioning. To examine this, we conducted a randomized controlled

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trial to determine whether access to an information-based website designed specifically for young women with breast cancer reduced anxiety and depression compared to usual care which included women's usual access to breast cancer resources over a six month period. We also examined whether access to the intervention reduced unmet needs and increased quality of life (secondary outcomes) compared to usual care.

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Method

Design. Prospective RCT with young, female breast cancer survivors approximately six-months post diagnosis at recruitment. Participants were randomised to either the intervention (IG) or usual care (UCG) groups and then completed the baseline questionnaire.

Sample

Eligible participants were between 18 and 50 years when diagnosed with stage I or II breast cancer, registered with the population based Victorian Cancer Registry (VCR) within 5 months of their diagnosis, considered capable of study participation by their clinician, had access to the internet and could understand written and spoken English. Women with a previous diagnosis of cancer or a prognosis less than 18-months were excluded.

Procedures

The VCR identified eligible women and contacted their clinician by mail to inform them of the study and confirm eligibility. If the clinician did not inform the VCR otherwise, the VCR sent a letter to eligible women informing them of the study and asking for their consent to pass their details on to the researchers. The research team approached consenting patients by mail, informed them that the study involved testing a web-based program designed to help women find the information and resources they need, when they needed them, and obtained written consent for

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study participation. Women not responding to the VCR's or researchers' letters within three weeks were resent the information and consent letter.

Consenting women were randomised to the IG or UCG using a computer generated 1:1 randomisation sequence. Women were sent baseline surveys after randomisation and upon baseline survey return were informed of their assigned study group, with IG women provided with website login information. A reminder about accessing the website was included in subsequent survey mail outs. The study had Institutional Human Research Ethics approval.

Study Arms

Usual Care Group (UCG): Participants in this group received usual care from their treating clinicians. While UCG participants could not access the intervention website, there were no restrictions on their access to other websites or resources.

[insert Figure 1 around here]

Intervention Group (IG): The '*informe*' (Information for Me) website is a self-directed information resource for young women with breast cancer. The website was organised around the different stages of breast cancer treatment: diagnosis, treatment (surgery, radiotherapy, chemotherapy and hormonal therapy/targeted therapy), and survivorship. The website also had sections covering emotional responses, support services, family responses and life after cancer. Figure 1 shows the home page and example topic pages from the website. A key organising principle was not to replicate resources developed by other breast cancer organisations. Instead '*informe*' aimed to link women to existing resources thereby providing the information women wanted while alerting them to relevant organisations or websites. Women were invited to monitor their emotional state using the thermometer image from the distress thermometer(Jacobsen, Donovan et al. 2005). Women completing the distress thermometer were provided with feedback regarding how they were doing with, for example, women scoring between 0-4 receiving a message saying they "seem to be doing OK'. Women with scores over 8 received a message indicating that they seemed to be 'very distressed at the moment' with the suggestion that they talk to their doctor about how they are feeling or call the Cancer Information and Support Service (CISS), a free service run by the leading cancer control organisation in the state of Victoria which is staffed by

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oncology nurses trained in the provision of information and support. Women were invited to complete the distress thermometer every time they logged onto the website. Distress scores were compared to previous scores and women with distress levels above 8 on two consecutive assessments received a message indicating that their stress or worry had remained high and a strong recommendation to contact their doctor or CISS. Project staff contacted these women by phone to check how they were and if needed linked them to CISS for further support. During the project only 4 women had scores of 8+ on two consecutive assessments. The website also offered a diary function for women to record their thoughts or feelings. Women could access '*informe*' as often as they liked, whenever they liked over a six-month study period. All resources on the website could be downloaded and at the end of each session, the information accessed could be collated for printing or download.

Information provided on '*informe*' was source from leading cancer or breast cancer specific organisations across Australia (e.g. Cancer Council Australia, National Breast Cancer Association), women's health sites and when necessary international sites. Where possible resources directed towards young women were sourced. However if this was not possible more generic resources were provided. All information on the website was reviewed for accuracy and completeness by a panel of health professionals which included an experienced breast surgeon, cancer nurses attached CISS. Consumers also reviewed the content on the website. '*informe*' was designed by professional web and graphic designers. A consumer reference group reviewed the design, content and functionality of the website.

Measures

Unless otherwise specified, all items were asked in the three questionnaires for both the IG and UCG. Baseline questionnaires collected sociodemographic characteristics including age, marital status and education. All surveys assessed treatment details. Study questionnaires were self-administered at study entry (baseline (T1)), then three months (first follow-up (T2)) and six months (second follow-up (T3)) later.

Primary outcomes:

The anxiety (7-items) and depression (7 items) subscales of the Hospital Anxiety and Depression Scale (HADS)(Zigmond and Snaith 1983, Snaith 2003) were the primary

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outcomes. Scores for each sub-scale range from 0 to 21 with high scores indicating higher levels of anxiety or depression. On each subscale scores can be classified into low/normal (0–7), borderline (8–10) or clinically significant (≥11). Internal reliability for each scale is high (Bjelland, Dahl et al. 2002).

Secondary outcomes:

Quality of Life: The 37-item Functional Assessment of Cancer Therapy – Breast (FACT-B)(Brady, Cella et al. 1997) assessed quality of life. FACT-B is a 37-item scale assessing general and breast cancer specific issues. The scale has high internal consistency (overall scale alpha=0.90), high test-retest reliability (0.85) and a demonstrated ability to discriminate between patients with different performance status(Brady, Cella et al. 1997).

Unmet supportive care needs: The 55 item Supportive Care Need Survey-Breast Cancer (SCNS-BC)(Boyes, Zucca et al. 2010) assessed unmet needs in the domains of: psychological (22 items); the health system and information (15 items); patient care and support (8 items); physical and daily living (7 items); sexuality (3 items); with four items assessing a mix of issues including transport to hospital and talking to others. For each item, respondents indicate their need for help in the past month on the scale: no need; need met; low; moderate; or high need. The SCNS-BC was included in all surveys completed by the IG. To avoid highlighting unmet needs to the UCG during the intervention period, only the final UCG survey contained these items. In this study, the number of low, moderate or high needs (any needs) and the number of moderate or high needs reported at each survey was summed to give the number of any needs and moderate/high needs experienced.

Health professional/peer support services used*:* In the final survey, participants indicated their use of five different health professionals (social workers, psychologists, counsellor, breast care nurse and general practitioners), and peer support services. The number of services used was summed.

Access to information sources: Participants also indicated whether they accessed four specific consumer resources with two resources web-based, one telephone based and one a drop-in centre.

Process measures. *(Web program access – IG only):* Date and time each website page was accessed by each participant was recorded as was the title of the page

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viewed. Total viewing time was determined by adding each page's viewing time. The number of days the website was accessed was recorded. Use of the distress thermometer was assessed.

Statistical Analyses

Analyses were conducted using STATA©. An intention-to-treat primary analysis was utilized. Generalized estimating equations (GEE) that included study arm, a categorical indicator of time and the interaction between group and time were generated. Intervention effects are presented as estimated mean differences in outcome variables between the two randomized arms, with 95% CIs and Wald test P values at the two follow-up times. Likelihood ratio tests examined the significance of the overall interaction providing an indication of the intervention's effectiveness across the entire study period. Chi-square tests and t-tests examined differences in use of the website between women with and without moderate/high needs. t-tests examined differences in the number of unmet needs and the number of support services used between IG and UCG. Assumptions underlying each analytic test were examined. While the distributions of some outcome variables were slightly skewed, this was not substantial enough to warrant transformation of variables. For all analyses two-sided p-values are reported.

Power calculations showed that 145 patients were needed in each group at the end of the trial assuming statistical power of 0.80 and an effect size of at least 0.33 SD on the HADs anxiety scale.

Results

Patient clinical and demographic details

[insert Figure 2 around here]

[insert Table 1 around here]

Figure 2 shows flow of participants through the trial. Of the 1316 eligible patients the VCR identified, 513 (39%) released their contact details to the researchers. Of these 394 (76%) consented to study participation and were randomised. Baseline questionnaires were returned by 177 UCG participants (97% response), and 202 IG

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participants (96% response). 90% (n=341) of baseline participants returned T2 questionnaires, and 299 T2 participants (76%) returned T3 questionnaires.

Demographic characteristics and clinical details of the IG and UCG were similar (Table 1). Women were on average 7 months post-diagnosis at study entry, with an average age of 44 years. Slightly more UCG women than IG women were in paid employment before their diagnosis. Treatment was similar for women in the two groups.

Unmet needs among IG women

[insert Table 2 around here]

At Baseline, women in the IG reported on average 21.6 (SD=13.4) needs and an average of 11.9 (SD=11.1) moderate/high needs. At Baseline (T1), 26% of the IG reported 20 or more moderate/high unmet needs (Table 2). The most common moderate/high need at T1 was dealing with 'fears relating to the cancer returning' (Table 2). By T2, the average number of needs had declined and 14% reporting 20 or more moderate/high needs (Table 2). The most common need at T2 was 'dealing with menopause symptoms' (36%). Similar proportions of IG and UCG participants reported any needs and moderate to high needs at T3 and the top 3 needs for both groups at this time concerned managing menopause symptoms, dealing with fatigue and fears about cancer spreading/returning (Table 2).

Engagement with the '*informe*' website

[insert Table 3 around here]

Table 3 shows details regarding website access over the six-month study period. While 70% of the IG accessed '*informe*', women most commonly did this only once (number of days accessed: median=1, range: 1-15) (Table 3). Of women accessing '*informe*' 83% used the distress thermometer, with 48% using it only once. The average distress thermometer score at first measure was 4.4 (SD=2.5). Although slightly more women with moderate/high unmet needs at T1 and T2 used the distress thermometer, these differences were not significant. The median total time spent on the website was 19 minutes (range:1-315) with 24% spending over 40 minutes. Women viewed a median of 15 (1-110) pages on each website visit. Having any moderate/high needs at T1 or T2 was not associated with accessing the

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website (Table 3). Women currently undergoing chemotherapy (n=18) spent a longer total time on '*informe*' (median=34, range:3-315) than women who had finished chemotherapy (n=90) (median=16.5, range:1-218) and those not having chemotherapy (n=57) (median=15, range:1-143) ($p<0.05$). No other treatment was related to website use.

The most commonly accessed web pages were: managing long term effects from treatment (45%), staying healthy after treatment (43%), dealing with fears of recurrence (41%), dealing with side-effects of tamoxifen (39%), finding support (39%) and finding a new normal (38%).

[insert Table 4 around here]

Primary Outcomes

The IG and the UCG did not differ in their average levels of anxiety or depression at T1 (Table 4) and anxiety and depression also did not differ between the two groups at T2 or T3. There was no significant effect of time and the interaction between study arm and time was not significant for anxiety ($\chi^2_{(df=2)}$=3.10, p=0.21), or depression ($\chi^2_{(df=2)}$=3.24, p=0.20).

Secondary Outcomes

Quality of life (FACT-B total): For the total scale there was a significant effect of time ($x^2_{(df=2)}$=8.29, p=0.02) and a significant interaction between study group and time ($\chi^2_{(df=2)}$=6.70, p=0.04). There was a greater increase in total quality of life for the IG than UCG between Time 1 and Time 2 ($\chi^2_{(df=1)}$=6.46, p=0.01) (Table 4). However change in total Fact-B scores between Time 1 and Time 3 did not differ between the IG and UCG. The increase in scores on the FACT-breast subscale between Time 1 and Time 2 was greater for the IG than the UCG (p=0.05), but change between Time 1 and Time 3 did not differ between the two groups and the interaction between study arm and time overall was not statistically significant (Table 4). For the Physical Well-being subscale, there was a significantly greater increase in scores between Time 1 and Time 2 for the IG than the UCG (p=0.05) although change between Time 1 and Time 3 was similar between the groups. The interaction between time and study arm was not significant for this subscale (Table 4). Scores on Functional Well-being improved over time in both groups (Table 4), with the interaction between study group and time not statistically significant.

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Unmet needs: The number of moderate/high unmet needs in the IG at T3 (mean=7.7) was similar to the number reported in the UCG (mean=8.3) (Table 4). The most common moderate to high unmet need in both groups was dealing with menopausal symptoms (IG: 36%; UCG: 38%). While the same needs were included in the top 10 moderate to high needs for the two groups, the order of the needs differed between the groups. For instance, dealing with a lack of energy was the second most common unmet need for the IG (29%) and fourth most common for the UCG (27%); fear of cancer spreading or returning was the third most common for the IG (29%) and the fifth most common for the UCG (26%). Being informed about possible causes and triggers of breast cancer was the second most common need for the UCG (29%) and the eighth most common for the IG (23%).

Number of health professional/peer support services used: The IG and UCG did not differ in the number of health professionals they talked to (Table 4).

Access to information resources: Greater proportions of the IG than UCG used the two internet-based support services and were aware of these services (Table 5). However, this difference was only statistically significant for the Government website ($\chi^2_{(df=2)}$=7.82, p=0.02) (Table 5). Combining data for the two websites, a greater proportion of IG women (73%) accessed either website compared to the UCG (62%) ($\chi^2_{(df=1)}$=3.85, p=0.05). While use of the telephone-based support service and the drop-in service was similar between the groups, fewer women in the UCG than IG were aware of these services, with this difference significant for the drop-in centre service ($\chi^2_{(df=2)}$=6.174, p=0.046).

[insert Table 5 around here]

Sub-group analyses: We tested whether the intervention was effective at reducing anxiety or depression in women with elevated (scores of 8+) on anxiety (UCG n=66; IG n=83) or depression (UCG n=33; IG n=41) at T1. No significant effect of the intervention was found for either anxiety or depression for this sub-group of women.

Discussion

This study examined whether access to an information-based website designed for young women with breast cancer reduced distress compared with usual care. While we found a high level of unmet supportive care needs among our study participants, we found no evidence of an intervention effect on our primary outcome measures. Of

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our secondary outcomes, we found a greater improvement in total quality of life and the quality of life subscales breast-related quality of life and physical well-being, for the IG than UCG between T1 and T2, although these improvements did not result in a significantly higher quality of life scores for IG women at this time point. Additionally, these quality of life scores did not differ between the two groups at T3. While we did not find an intervention effect on other secondary outcome measures, we did find that IG women were more likely to access a government run web-based information site and our results showed a general pattern where more IG women were aware of available information services than women in the UCG. Our results suggest that while access to our website did not assist women in reducing their information and supportive care needs, it may have helped to improve quality of life more rapidly and to have raised awareness of some other available internet resources.

The lack of an intervention effect on our primary outcomes is similar to findings from several trials of online educational programs that showed no intervention effect on distress measures including anxiety(Ryhänen, Rankinen et al. 2013, Ventura, Sawatzky et al. 2013). These results contrast to findings of trials involving more intensive online programs with, for instance, one study finding participation in a 16-week online self-management program significantly lowered distress compared to usual care, although there was no intervention effect on patient empowerment(van den Berg, Gielissen et al. 2015). However, this study also found that the intervention effect diminished over time(van den Berg, Gielissen et al. 2015). Studies examining the effectiveness of the computer-based Comprehensive Health Enhancement Support System (CHESS) with women with breast cancer have generally found a positive effect of the system on measures of patient participation in health care (Gustafson, Hawkins et al. 2001, Gustafson, Hawkins et al. 2008) with some(Gustafson, Hawkins et al. 2008) but not all (Gustafson, Hawkins et al. 2001) also finding positive overall effects on quality of life. Other studies examining the impact of self-management internet-based interventions have found positive effects on symptom distress(Ruland, Andersen et al. 2013, Borosund, Cvancarova et al. 2014), although effects on anxiety and depression are less clear, with one study finding positive effects on these outcomes(Borosund, Cvancarova et al. 2014), and another finding no effect on these outcomes or on quality of life.

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Given the positive effects for programs requiring participation over a number of weeks, a possible reason for our study's lack of intervention effect may the lower levels of engagement with the website. The majority of IG women in our study accessed the '*informe*' website only once, viewing on average 16 pages and spending a median of 19 minutes on the website. The data suggest that many women visiting the site did so to browse its contents. The low level of repeat visits suggests the website failed to engage the majority of women in the IG, reducing its ability to address information needs and raises questions regarding the acceptability of the website intervention. To ensure the website was attractive to women, we engaged an experienced web designer to build '*informe'* and undertook extensive consumer testing to refine the product to the point where consumers judged it to be of a high quality and capable of addressing the information needs of young women with breast cancer. Feedback from women suggested many found *'informe'* provided "a great amount of information available in easy to read terminology". Factors other than poor design may have contributed to the lack of engagement. While '*informe*' addressed many issues of relevance to young women with breast cancer (e.g. sexuality, fertility, premature menopause, partnering, talking to children, parents and partners) it did not address issues relating to work or provide substantial information on parenting while having treatment. The lack of information on these topics and other potential topics may have also contributed to reducing some women's engagement in the site.

Similar to the Breast Cancer e-Health trial(van den Berg, Gielissen et al. 2015), women in our study were around 7-months post-diagnosis when they commenced study participation. However, offering access to an information-based website to women who were around 7-months post diagnosis may be too late in their treatment trajectory(Beatty, Binnion et al. 2017). Our finding that IG women undergoing chemotherapy spent longer on the website suggests the intervention may have been more useful if it was offered when women are making decisions about, starting or undergoing different treatments.

While women in the UCG could not access the intervention website, we did not restrict their access to other breast cancer related websites or resources. While access to other websites by the UCG may have reduced any potential effect of the *'informe'* website, it allowed us to determine whether access to a specific breast

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cancer website provided additional benefit to young women with breast cancer compared to usual care. Although we didn't directly assess internet use by women in the IG or UCG, we did assess use of breast cancer specific websites and non-internet resources including use of health professional services. While use of health professionals and non-internet based resources (cancer helpline and a breast cancer drop-in centre) was similar for the IG and UCG, women in the IG were more likely to access breast cancer websites and/or be aware of these resources. The greater use of these breast cancer specific websites by the IG, suggests that the lack of intervention effect was not due to equivalent use of internet-based breast cancer resources between the two study groups.

Similar to previous studies(Thewes, Meiser et al. 2005, Howard-Anderson, Ganz et al. 2012, Ruddy, Greaney et al. 2013) we found a high level of unmet needs among young women with breast cancer with nearly 90% reporting at least one and 43% reporting more than 10 moderate/high needs at baseline. The most common needs reported at baseline concerned dealing with fears of cancer recurrence, dealing with fatigue and wanting age appropriate information. At T2, the most common unmet needs concerned managing menopause systems. '*informe*' provided age appropriate information that attempted to address the needs women reported. As web pages relating to fear of recurrence, managing effects from treatment, and understanding side effects from tamoxifen were some of the most frequently accessed, '*informe*'s' content matched the needs women reported. While '*informe*' provided strategies that might be used to address different needs, it did not include coaching or behavioural change techniques to assist with the adoption of these strategies. In addition the website's design was non-directive, with women accessing the components of the website they were interested rather than working through modules following a specified order. The success of the 16-week internet-based program for women with breast cancer discussed above in reducing distress at least in the short term(van den Berg, Gielissen et al. 2015) suggests that structured approaches are more effective than non-structured websites. However as a trial involving prostate cancer patients did not find a significant effect on distress for those participating in the structured online program study-arm(Wootten, Abbott et al. 2015), further work examining the elements of a successful online intervention program is needed.

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We did not find any difference in the number of unmet needs IG and UCG women reported at the final survey. The number of unmet needs reported by IG women reduced significantly over the study period, with needs reducing between each measurement point. A systematic review of randomised control trials to reduce unmet needs of cancer patients identified nine trials of which six did not find an intervention effect(Carey, Lambert et al. 2012). The authors suggested that the lack of intervention effect may be due to unmet needs reflecting the uncertainty and need for reassurance many patients with a life threatening illness desire(Carey, Lambert et al. 2012). Our pattern of decreasing needs may reflect young women's progression through their treatment and into survivorship.

Similar to other trials testing interventions to improve well-being or address unmet needs of cancer patients(Aranda, Schofield et al. 2006, Girgis, Breen et al. 2009, Livingston, White et al. 2010, White, Macvean et al. 2012), we took a population approach to the delivery of the intervention and offered all women the opportunity to participate in the study regardless of their level of distress. The average level of anxiety and depression among participants at the start of our study was within the normal range for non-clinical samples(Crawford, Henry et al. 2001) suggesting any disease-related anxiety and depression that patients may have experienced had largely dissipated by the time women completed the baseline survey. Hence, the lack of intervention effect on anxiety and depression may have been due to the relatively normal levels of distress in our study sample to begin with. Like other studies in this area(Galway, Black et al. 2012) our strategy of testing the intervention on young breast cancer patients regardless of their level of need or distress may have reduced the ability of the intervention to produce an effect.

Our study has a number of strengths that need to be noted, including the large sample size, the randomized design and the use of validated outcome measures. The involvement of consumers in the design of the website is also a strength of our study. However, a number of study limitations that need to be noted. As participants were not blind to the study arm they were assigned to, participants in the UCG may have sought other avenues for support or information once they understood they did not have access to the website. However, we note that our results showed similar or lower use of a number of breast cancer specific or cancer patient resources in the UCG compared to the IG. The participation rate for the study was low with 31% of

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women initially approached by the VCR about study participation agreeing to take part in the study and returning completed questionnaires. While this level of participation is similar to other studies using population based registries for recruitment(Thong, Mols et al. 2013), we are conscious that the low participation rate suggests we should not generalize the results of this study to the wider population of young women with breast cancer.

This study was designed to examine whether an information-based website that aimed to address the needs of young women with breast cancer could reduce anxiety and depression and improve the quality of life of these women. While we demonstrated that most women in this population group experience a relatively high level of unmet needs, our study did not find a significant effect of our intervention when offered to women who were on average 7-months post diagnosis.

The internet remains a key source of health information for cancer patients. As most readily accessible websites are information-based sites, further work is needed to understand how these resources can be designed to maximize their impact for users. Studies examining the impact of web-based therapeutic programs to reduce distress or anxiety in cancer patients frequently incorporate strategies such as reminder emails, personalised content, goal setting, videos and homework to increase user engagement(Wootten, Abbott et al. 2015, Beatty, Koczwara et al. 2016, Chambers, Ritterband et al. 2018). Identifying mechanisms for incorporating these strategies into information-based programs may help to increase user engagement and encourage repeat visits thereby helping to address information needs. While we worked with consumers to ensure relevance of information on the *INFORME* website, appeal and ease of navigation, future studies may benefit by working with consumers to identify the mechanisms and design features that encourage greater active participation with the website. Delivering information through multiple media (video, audio, written) and including online peer-to-peer forums may also help to engage users(Beatty, Binnion et al. 2017). Testing the website's content with consumers to ensure the information provided is both accurate and useful may also help to increase the utility of information-based websites(Beatty and Binnion 2016). Finally, the target audience for the intervention needs to be considered, with studies testing interventions to reduce psychological

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states such as anxiety and depression, needing to ensure that levels of morbidity at baseline are elevated sufficiently to allow room for an intervention effect(Galway, Black et al. 2012).

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Table 1. Demographic and clinical details of participants in the intervention and usual care groups at study entry and treatment details over life of project

	Usual Care Group (n =177)		**Intervention Group (n = 202)**	
Patient Characteristics	**Mean**	**(SD)**	**Mean**	**(SD)**
Age	43.9	(5.3)	43.6	(5.0)
Average number of months between diagnosis and return first survey	7.1	(2.1)	7.2	(2.1)
	n	**%**	**N**	**%**
Marital status				
married/defacto	134	76	163	82
Other	42	24	37	18
Highest Education				
primary	3	2	1	1
secondary	39	22	47	23
certificate/diploma	48	27	71	35
university degree	86	49	83	41
Work status				
Before diagnosis				
Employed (full, part or casual)	146	82	153	75
After diagnosis				
Employed (full, part or casual)	116	65	140	69
Private health insurance	126	71	140	69
Currently having treatment (Yes)	114	66	115	59
Patient Characteristics				
Cancer stage				
I	84	47	98	49
II	92	52	98	48
IIIA/IIIB	1	1	2	1
Treatment received				
surgery	175	100	202	100
chemotherapy	114	65	128	64
radiotherapy	103	59	117	58
targeted therapy	39	23	41	20
hormonal therapy	98	56	115	58

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Table 2. The proportion of intervention participants at baseline, Time 2 and Time 3 and usual care participants at Time 3, reporting no, 1-10, 11-20 or 21 or more low/moderate/high (any) needs and moderate/ high needs, the average number of any and moderate/high needs[#] and the five most commonly reported needs[##].

	Any unmet needs^	**Moderate or high unmet needs**
Intervention Group		
Baseline (T1)	**(n=202)**	**(n=202)**
no needs	5%	12%
1-10 needs	23%	45%
11-20 needs	21%	17%
21 + needs	52%	26%
Average number of needs (T1) (SD)	**21.6 (13.4)**	**11.9 (11.1)**
Five most commonly reported needs (T1)		
Dealing with fears about the cancer spreading or returning.	70%	45%
Dealing with lack of energy or tiredness.	64%	39%
Receiving information appropriate to your age	61%	36%
Changes to your usual routine or lifestyle	61%	29%
Being informed about the causes and possible triggers of breast cancer	60%	37%
Follow-up 1 (T2)	**(n=176)**	**(n=176)**
no needs	7%	27%
1-10 needs	35%	44%
11-20 needs	18%	15%
20 + needs	40%	14%

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	Any unmet needs^	**Moderate or high unmet needs**
Average number of needs (T2) (SD)	**17.9(14.7)**	**7.9 (10.1)**
Five most commonly reported needs (T2)		
Dealing with menopausal symptoms	62%	36%
Dealing with fears about the cancer spreading or returning.	58%	26%
Dealing with lack of energy or tiredness.	55%	27%
Being informed of latest developments in treatment	49%	24%
Coping with changes to sexuality or sexual relationships	47%	20%
Follow-up 2 (T3)		
no needs	6%	27%
1-10 needs	34%	41%
11-20 needs	20%	19%
20 + needs	39%	13%
Five most commonly reported needs (T3)		
Dealing with menopausal symptoms	62%	36%
Dealing with lack of energy or tiredness.	56%	30%
Dealing with fears about the cancer spreading or returning.	59%	29%
Receiving information specific to women your age	-	28%
Having one doctor that knows all about your condition and your treatment	-	27%

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	Any unmet needs^	Moderate or high unmet needs
Sexuality	51%	-
Learning about new treatment developments	49%	-
Usual Care Group		
Follow-up 2 (T3) (needs only assessed at this time point)		
no needs	11%	26%
1-10 needs	32%	44%
11-20 needs	20%	15%
20 + needs	36%	13%
Five most commonly reported needs (T2)		
Dealing with menopausal symptoms	58%	37%
Being information about possible causes and triggers of breast cancer	46%	29%
Receiving information specific to women your age	43%	28%
Dealing with lack of energy or tiredness	47%	27%
Dealing with fears about the cancer spreading or returning.	54%	26%
Having one doctor that knows all about your condition and your treatment	-	26%
Receiving information and advice about diet	-	26%
Learning about new treatment developments	43%	-

[#] not reported for Time 3 as shown in Table 4. [##] ordered by decreasing frequency for moderate to high needs.

^ count of the number of items women reported having a low, moderate or high need for help

^^ count of the number of items women reported having a moderate or high need for help

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Table 3. Website engagement among all intervention group participants and for those with any unmet needs and moderate/high unmet needs at first follow-up (Time 2) and second follow-up (Time 3).

			Time 2 (N=202)				**Time 3 (N=171)**			
	All intervention participants		Any needs (N=193)		Any mod/high needs (N=178)		Any needs (N=159)		Any mod/high needs (N=124)	
Engagement with intervention	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Accessed website	143	(70%)	135	(70%)	124	(70%)	127	(80%)	102	(82%)
Used distress thermometre at least once	119	(59%)	13	(52%)	106	(60%)	27	(56%)	84	(66%)
	Median	(range)	Median (range)		Median (range)		Median (range)		Median (range)	
Number of days website accessed	1	(1-15)	1 (1-13)		1(1-15)		1(1-15)		1 (1-13)	
Total time spent on website (minutes)	19	(1-315)^	20 (1-315)		21 (1-218)		18 (1-315)		21.5 (1-315)	
Total number of website pages viewed	16	(1-166)^^	16 (1-166)		16 (1-166)		16 (1-166)		16.5 (1-166)	

^ 13 women spent more than 100 minutes on the website with only 1 spending 315 minutes

^^ only 7 women viewed more than 100 pages with 2 viewing more than 150

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Table 4. Mean scores and standard deviations (SD) for the primary (HADs Anxiety and Depression) and secondary (FACT-B quality of life and unmet needs) outcome measures and number of information and support services used for intervention (IG) and usual care groups (UCG) at each survey.

Domain	Usual care Group (n = 175) Mean (SD)	Intervention Group (n = 202) Mean (SD)	Study Arm p-value	Time p-value X2, p-value	Interaction Study arm by time X2, p-value
Primary outcomes					
HADS Anxiety					
Baseline	6.5 (4.2)	6.6 (4.0)	0.93		
Time 2	6.9 (4.6)	6.4 (4.1)	0.36	3.18, df=2,	3.10, df=2,
Time 3	6.5 (4.1)	6.2 (3.7)	0.80	P=0.20	P=0.21
HADS Depression					
Baseline	4.1 (3.6)	4.4 (3.3)	0.23		
Time 2	3.9 (3.9)	3.5 (3.1)	0.43	1.42, df=2	3.24, df=2
Time 3	3.5 (3.6)	3.4 (3.5)	0.79	P=0.49	P=0.20
Secondary Outcomes					
FACT-Breast total					
Baseline	102.8 (20.0)	100.0 (19.7)	0.23		
Time 2	105.4 (21.0)	106.2 (19.5)	0.89	8.29, df=2	6.7, df=2
Time 3	109.5 (19.6)	107.9 (19.2)	0.10	P=0.02	P=0.04
FACT-breast					

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Domain	Usual care Group (n = 175) Mean (SD)	Intervention Group (n = 202) Mean (SD)	Study Arm p-value	Time p-value X2, p-value	Interaction Study arm by time X2, p-value
Baseline	25.0 (7.1)	24.2 (7.5)	0.30		
Time 2	26.1 (7.3)	26.4 (6.9)	0.80	2.22, df=2	3.75, df=2
Time 3	26.7 (7.0)	26.4 (7.0)	0.34	P=0.33	P=0.15
FACT emotional well being					
Baseline	18.2 (4.0)	17.8 (3.9)	0.43		
Time 2	18.3 (4.3)	18.4 (4.2)	0.90	2.59,df=2,	1.86, df=2,
Time 3	18.9 (3.8)	18.6 (3.8)	0.15	P=0.27	P=0.39
FACT Physical well being					
Baseline	21.2 (5.3)	20.3 (5.4)	0.11		
Time 2	22.5 (4.4)	22.5 (4.6)	0.86	5.71, df=2,	4.12, df=2,
Time 3	23.6 (4.2)	23.3 (4.2)	0.22	P=0.06	P=0.13
FACT functional Well being					
Baseline	19.2(5.6)	18.8 (5.4)	0.49		
Time 2	20.2 (5.8)	20.5 (5.3)	0.77	7.92, df=2,	2.85, df=2,
Time 3	21.4 (5.4)	21.1 (5.2)	0.19	P=0.02	P=0.24
FACT social well being					
Baseline	19.0 (4.6)	18.8 (4.7)	0.56		
Time 2	18.4 (5.1)	18.4 (4.5)	0.99	2.83, df=2,	1.56, df=2,

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Domain	Usual care Group (n = 175) Mean (SD)	Intervention Group (n = 202) Mean (SD)	Study Arm p-value	Time p-value X2, p-value	Interaction Study arm by time X2, p-value
Time 3	18.9 (5.1)	18.4 (4.8)	0.16	P=0.24	P=0.46
Unmet needs Time 3					
Any needs	12.9 (14.1)	13.5 (14.3)	0.65	n/a	n/a
Moderate/high needs	8.3 (10.4)	7.7 (9.4)	0.61	n/a	n/a
Health professionals discussed with Time 3					
Average number Health professionals	1.3 (1.2)	1.2 (1.2)	0.16	n/a	n/a

Table 5: Proportion of women in the intervention (IG) and usual care groups (UCG) reporting use, non-use and lack of awareness of different breast cancer resources at second follow-up (Time 3).

		Level of Service use			
Resource used	**Study arm**	**Used N (%)**	**Did not use N (%)**	**Not aware of service N (%)**	**p-value**
Cancer Council	UCG	11 (9%)	206 (84%)	9 (7%)	
Telephone helpline	IG	15 (11%)	114 (86%)	3 (2%)	P=0.152

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Breast cancer telephone information line or resource centre	UCG	24 (18%)	87 (64%)	24 (18%)	
	IG	25 (17%)	105 (72%)	16 (11%)	P=0.223
Breast Cancer drop-in Centre	UCG	13 (10%)	82 (61%)	39 (29%)	
	IG	13 (9)	105 (74%)	24 (17%)	P=0.046
Breast Cancer Consumer advocacy/support website	UCG	85 (62%)	45 (33%)	7 (5%)	
	IG	111 (73%)	39 (26%)	3 (2%)	P=0.100
Government breast cancer information website	UCG	43(32%)	70 (52%)	22 (16%)	

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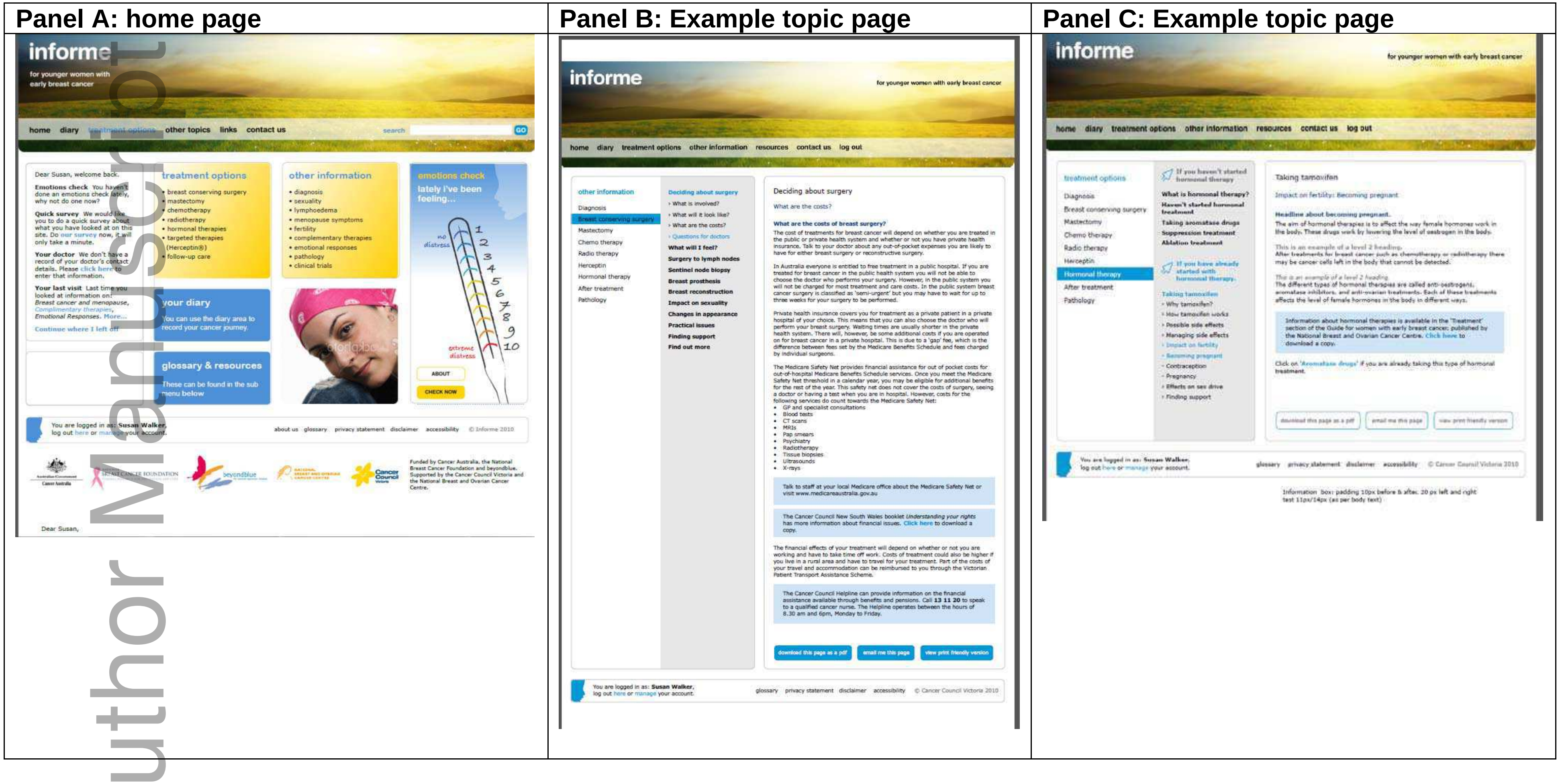

Panel A: home page

Dear Susan, welcome back.

Emotions check You haven't done an emotions check lately, why not do one now?

Quick survey We would like you to do a quick survey about what you have looked at on this site. Do our survey now, it will only take a minute.

Your doctor We don't have a record of your doctor's contact details. Please click here to enter that information.

Your last visit Last time you looked at information on: *Breast cancer and menopause*, *Complimentary therapies*, *Emotional Responses*. More...

Continue where I left off

treatment options

- breast conserving surgery
- mastectomy
- chemotherapy
- radiotherapy
- hormonal therapies
- targeted therapies (Herceptin®)
- follow-up care

other information

- diagnosis
- sexuality
- lymphoedema
- menopause symptoms
- fertility
- complementary therapies
- emotional responses
- pathology
- clinical trials

your diary

You can use the diary area to record your cancer journey.

glossary & resources

These can be found in the sub menu below

You are logged in as: **Susan Walker**, log out here or manage your account.

Funded by Cancer Australia, the National Breast Cancer Foundation and beyondblue. Supported by the Cancer Council Victoria and the National Breast and Ovarian Cancer Centre.

Dear Susan,

Panel B: Example topic page

Deciding about surgery

What are the costs?

What are the costs of breast surgery?

The cost of treatments for breast cancer will depend on whether you are treated in the public or private health system and whether or not you have private health insurance. Talk to your doctor about any out-of-pocket expenses you are likely to have for either breast surgery or reconstructive surgery.

In Australia everyone is entitled to free treatment in a public hospital. If you are treated for breast cancer in the public health system you will not be able to choose the doctor who performs your surgery. However, in the public system you will not be charged for most treatment and care costs. In the public system breast cancer surgery is classified as 'semi-urgent' but you may have to wait for up to three weeks for your surgery to be performed.

Private health insurance covers you for treatment as a private patient in a private hospital of your choice. This means that you can also choose the doctor who will perform your breast surgery. Waiting times are usually shorter in the private health system. There will, however, be some additional costs if you are operated on for breast cancer in a private hospital. This is due to a 'gap' fee, which is the difference between fees set by the Medicare Benefits Schedule and fees charged by individual surgeons.

The Medicare Safety Net provides financial assistance for out of pocket costs for out-of-hospital Medicare Benefits Schedule services. Once you meet the Medicare Safety Net threshold in a calendar year, you may be eligible for additional benefits for the rest of the year. This safety net does not cover the costs of surgery, seeing a doctor or having a test when you are in hospital. However, costs for the following services do count towards the Medicare Safety Net:

- GP and specialist consultations
- Blood tests
- CT scans
- MRIs
- Pap smears
- Psychiatry
- Radiotherapy
- Tissue biopsies
- Ultrasounds
- X-rays

Talk to staff at your local Medicare office about the Medicare Safety Net or visit www.medicareaustralia.gov.au

The Cancer Council New South Wales booklet *Understanding your rights* has more information about financial issues. Click here to download a copy.

The financial effects of your treatment will depend on whether or not you are working and have to take time off work. Costs of treatment could also be higher if you live in a rural area and have to travel for your treatment. Part of the costs of your travel and accommodation can be reimbursed to you through the Victorian Patient Transport Assistance Scheme.

The Cancer Council Helpline can provide information on the financial assistance available through benefits and pensions. Call **13 11 20** to speak to a qualified cancer nurse. The Helpline operates between the hours of 8.30 am and 6pm, Monday to Friday.

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Panel C: Example topic page

Taking tamoxifen

Impact on fertility: Becoming pregnant

Headline about becoming pregnant.

The aim of hormonal therapies is to affect the way female hormones work in the body. These drugs work by lowering the level of oestrogen in the body.

This is an example of a level 2 heading.

After treatments for breast cancer such as chemotherapy or radiotherapy there may be cancer cells left in the body that cannot be detected.

This is an example of a level 2 heading.

The different types of hormonal therapies are called anti-oestrogens, aromatase inhibitors, and anti-ovarian treatments. Each of these treatments affects the level of female hormones in the body in different ways.

Information about hormonal therapies is available in the 'Treatment' section of the Guide for women with early breast cancer, published by the National Breast and Ovarian Cancer Centre. Click here to download a copy.

Click on 'Aromatase drugs' if you are already taking this type of hormonal treatment.

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Information box: padding 10px before & after. 20 px left and right
text 11px/14px (as per body text)

Figure 1. Example of home page and different topic pages in the informe website.

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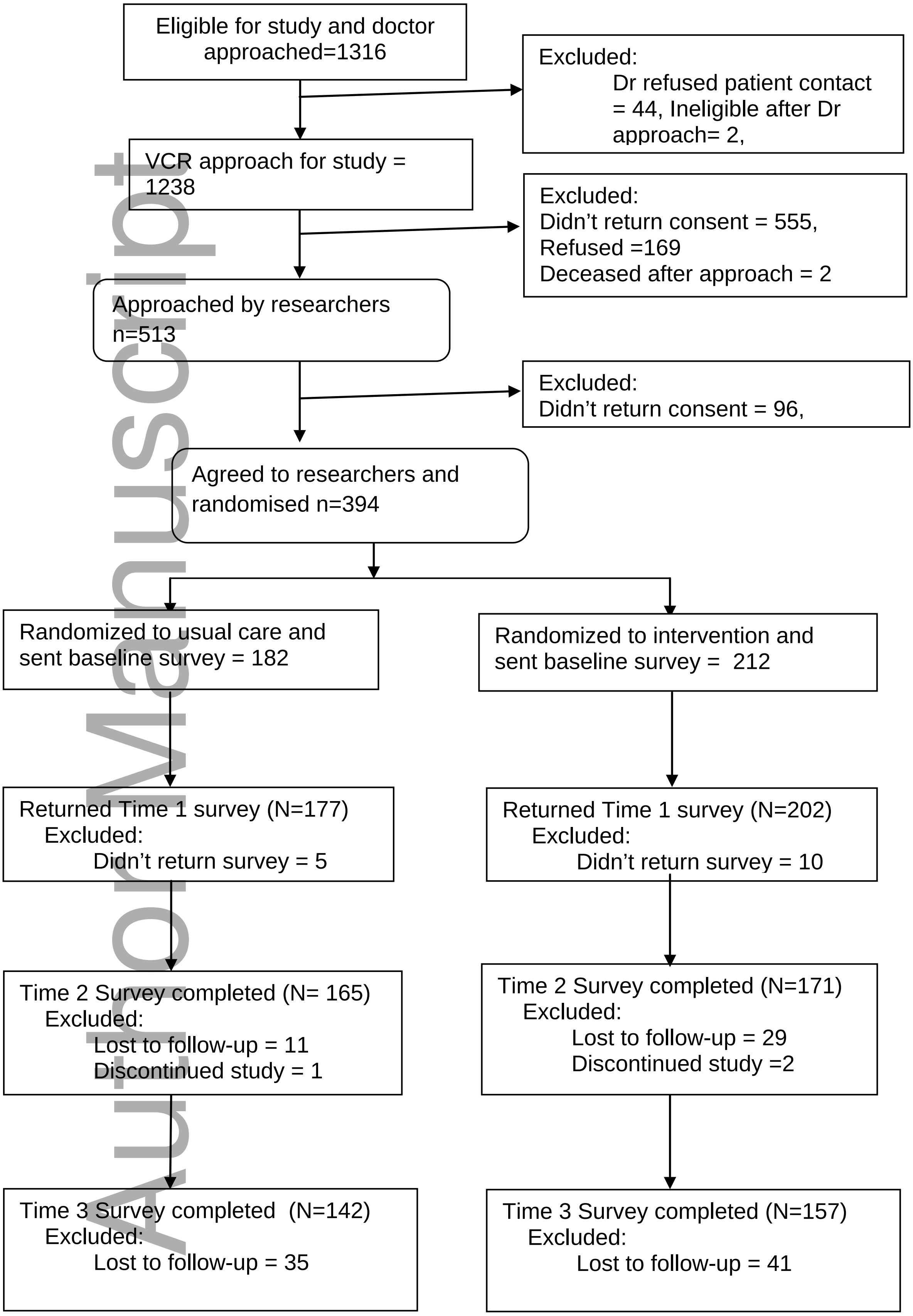

Figure 2. CONSORT diagram of recruitment and attrition

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