A Guide To Genetic Consenting

Module 12: eHealth model

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This information has been organised and fully funded by AstraZeneca and MSD in collaboration with the Central European Cooperative Oncology Group (CECOG).
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Z4-45933
Date of preparation: June 2022

Learning objectives

The primary purpose of this learning module is to inform and educate non-genetics HCPs on genetic consenting.

This module will enable HCPs to:

- Be aware of alternative models of genetic consenting
- Understand how genetic testing can guide treatment decisions in cancer

HCP=healthcare professional

eHealth genetic counselling provides web-based delivery of genetic education and post-test results disclosure to patients

The eHealth model uses information and communication technologies to provide online genetic counselling services

Online access to genetic testing and counselling for patients with cancer or those at risk for hereditary cancer has the potential to overcome the barriers associated with current models, particularly:

- Limitations to physician time and knowledge
- Accessibility and flexibility[1]

Web-based genetic counselling services may include:

Professional videos[2]

E-learning modules[2]

Chatbots[3]

Data collection[3]

Genetic results delivery[4]

1. Rayes N, et al. *BMC Cancer*. 2019;19:648; 2. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04447703 (Accessed May 2022); 3. Kaphingst K, et al. *BMC Health Serv Res*. 2021;21:542; 4. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04353973 (Accessed May 2022)

Several studies are evaluating the impact of eHealth genetic counselling on patients with or at high-risk for hereditary cancer

MAGENTA[1]	**Study aim:** To study how well online genetics educational videos with or without pre- and/or post-test telephone genetic counselling work in assessing cancer risk distress in pre-specified groups of breast cancer patients and the relatives of cancer patients
BRCA-DIRECT[2]	**Study aim:** To evaluate whether digital delivery of pre-test information for BRCA testing in patients with breast cancer is non-inferior to current standard practice of 1:1 delivery from a healthcare professional, as measured by rate of uptake of the genetic testing
eReach[3]	**Study aim:** To determine whether web-based eHealth delivery of pre-test and/or post-test genetic counselling can provide equal or improved cognitive and affective short-term and 6-month outcomes compared to the two-visit SoC delivery model with a genetic counsellor
TARGET[4]	**Study aim:** To perform user testing of a mobile-friendly patient history collection and genetics education tool, and assess how this web-based genetics tool compares to traditional genetic counselling to provide genetic testing to men with prostate cancer

[a]Primary completion date

SoC=standard of care; TNBC=triple negative breast cancer

1. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02993068 (Accessed Ju;y 2022); 2. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04842799 (Accessed Ju;y 2022); 3. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04353973 (Accessed July 2022); 4. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04447703 (Accessed July2022)

The MAGENTA study will assess the effectiveness of online genetics education in assessing cancer-risk distress in patients with TNBC

Study aim

To study how well online genetics educational videos with or without pre- and/or post-test telephone genetic counselling work in assessing cancer-risk distress in pre-specified groups of breast cancer patients and the relatives of cancer patients

Demographics

Aged ≥30 y/o

Participants must meet ≥1 of the following criteria:

- BC diagnosis at ≤45 y/o
- TNBC diagnosis at ≤60 y/o
- Relative that has at least one HRR gene mutation[a]
- Relative with OC
- ≥2 relatives with BC on the same side of the family, one of which is ≤50 y/o
- Male relative with BC

Primary outcome

- Mean cancer stress scores[b]

N=4000

Arm A	• Online genetics education and test report • No telephone genetic counselling
Arm B	• Online genetics education and test report • Post-test telephone genetic counselling
Arm C	• Online genetics education and test report • Pre- and post-test telephone genetic counselling
Arm D	• Online genetics education and test report • Pre-test telephone genetic counselling

[a]HRR mutations defined as *BRCA1, BRCA2, BRIP1, PALB2, RAD51C, RAD51D, BARD1, MSH2, MSH6, MLH1* or *PMS2*

[b]The Impact of Events Scale is a 15-item self-report measure that assesses subjective distress caused by traumatic events, which may include a positive genetic test result. There are two subscales, intrusion and avoidance, which are used to calculate the total. The range for intrusion is 0–35 and the range for avoidance is 0–40. The range of the total score is 0–75 and subscales are summed to compute the total score. Higher scores reflect more stressful impact and therefore worse outcome

BC=Breast cancer; HRR=homologous recombination repair; N=population sample number; OC=ovarian cancer; TNBC=triple negative breast cancer; y/o=years old

1. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02993068 (Accessed July 2022)

The BRCA-DIRECT study will assess the effectiveness of digital delivery of pre-test information for BRCA testing in patients with breast cancer

Study aim

To evaluate whether the digital delivery of pre-test information for BRCA testing in patients with BC is non-inferior to current standard practice of 1:1 delivery[a] from a healthcare professional, as measured by rate of uptake of the genetic testing

Demographics

Aged >18 y/o

Inclusion criteria:
- Female
- Diagnosis of invasive BC or high-grade DCIS

Exclusion criteria:
- Previous testing for BRCA

N=1000

Arm A
- Digital delivery of genetic pre-test information

Arm B
- Genetic counselling telephone appointment to discuss genetic pre-test information

Primary outcome

- Uptake of genetic testing[b]

Secondary outcomes

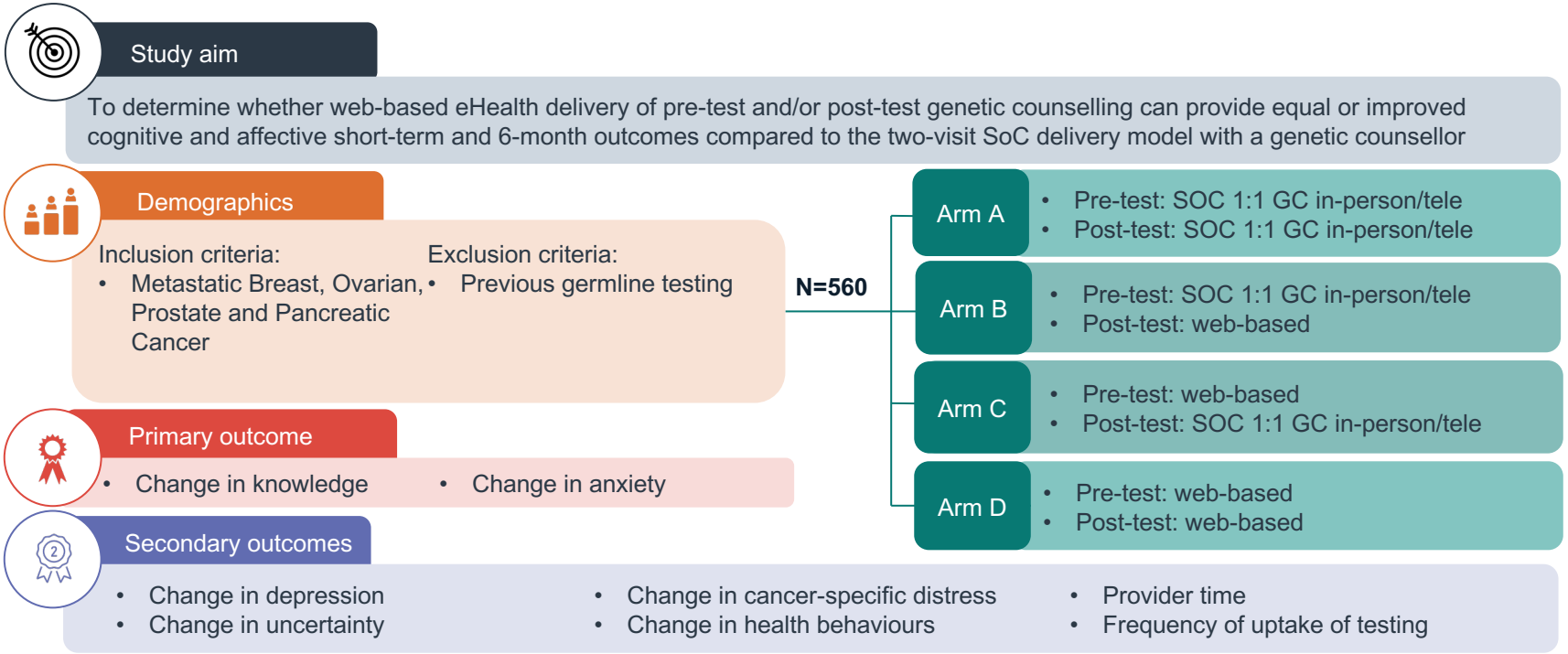
- Knowledge about BRCA testing
- Anxiety following delivery of pre-test information and test results
- Uptake of digital genetic testing
- Time to results[c]
- Helpline usage
- HCP satisfaction
- Patient satisfaction

[a]Telephone consultation with a genetic counsellor (standard of care); [b]Time frame: from the point the participant completes the initial expression of interest form at enrolment, until the participant completes the BRCA test consent approx. 1–3 weeks later; [c]Time frame: the point at enrolment where the participant completes the expression of interest form until the notification that the patients BRCA test results are available (approx. 6–8 weeks)

BC=breast cancer; DCIS=ductal carcinoma in situ ; GC=genetic counsellor; HCP=healthcare professional; y/o=years old

1. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04842799 (Accessed July 2022)

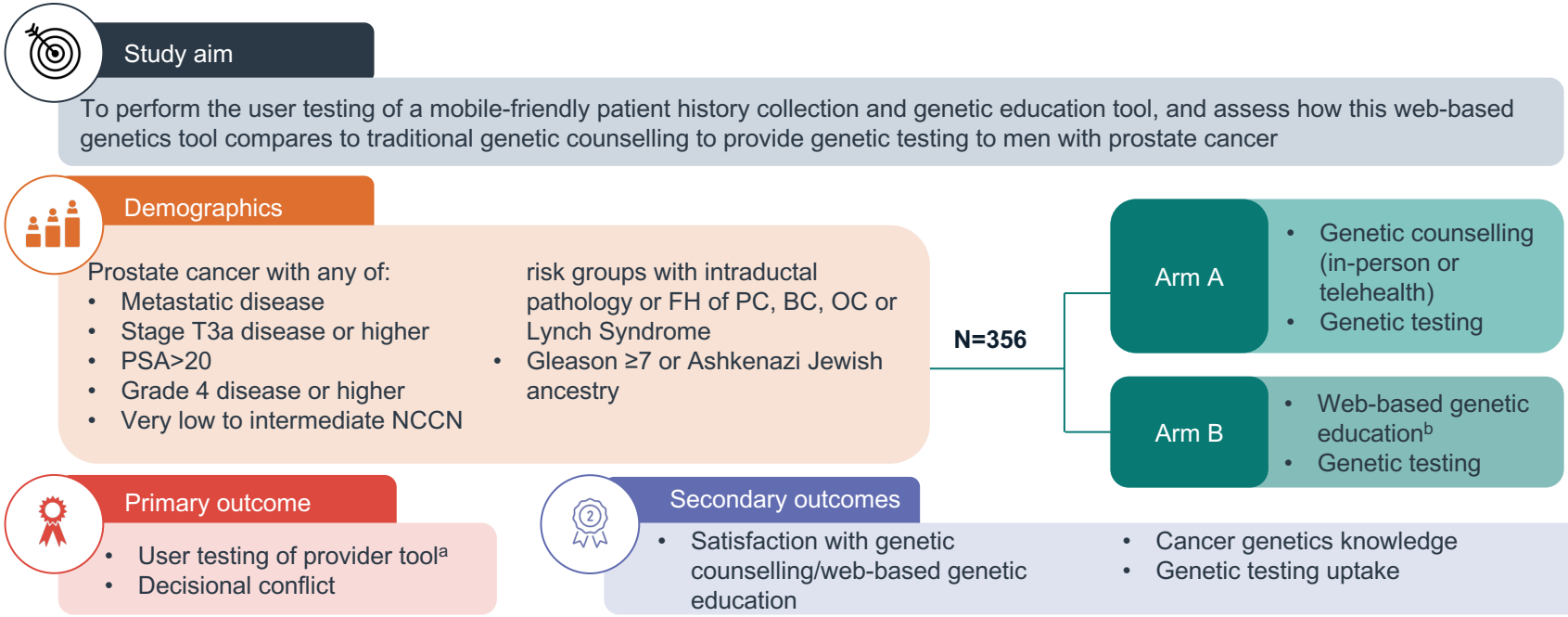
The eReach study will investigate the impact of web-based eHealth delivery of genetic counselling on patients with or at high risk for cancer



BC=breast cancer; BRCA=BReast CAncer gene 1/2; DCIS=ductal carcinoma in-situ; GC=genetic counselling; y/o=years old; SOC=standcard of care

1. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04353973 (Accessed July 2022)

The TARGET study will assess the effectiveness of a web-based genetic education tool for providing genetic testing to men with prostate cancer



[a]Will be assessed for non-inferiority between study arms and evaluated using the O'Connor decisional conflict scale, which captures subscores over 16 questions for uncertainty, feeling of being informed, values clarity, support and effective decision-making on a 5-point Likert scale; [b]Patients may cross-over to Arm I to see a genetic counsellor

BC=breast cancer; FH=family history; OC=ovarian cancer; PC=prostate cancer; PSA=prostate specific antigen; y/o=years old

1. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04447703 (Accessed July 2022)

Summary

- The eHealth model uses information and communication technologies to provide online genetic counselling services[1]

- Several studies are evaluating the impact of eHealth genetic counselling on patients with or at high-risk for hereditary cancer[2-5]

1. Rayes N, et al. *BMC Cancer*. 2019;19:648; 2. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02993068 (Accessed July 2022); 3. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04842799 (Accessed July 2022); 4. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04353973 (Accessed July 2022); 5. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04447703 (Accessed July 2022)