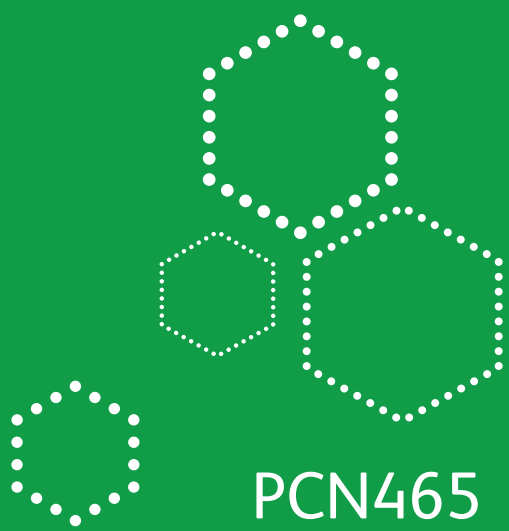




Virtual Community Engagement Among Women Receiving Palbociclib for HR+/HER2– Metastatic Breast Cancer: Data From the MADELINE Study

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BACKGROUND

- In the United States (US) in 2019, there were an estimated 268,600 incident cases of and 41,760 deaths from breast cancer, the most common cancer among US women. Estimated 5-year survival for women with metastatic disease is 27 %.¹
- The most common breast cancer subtype among US women is hormone receptor-positive (HR+)/human epidermal growth factor receptor 2–negative (HER2–).²
- The US Food and Drug Administration has approved palbociclib for the treatment of HR+/HER2– advanced or metastatic breast cancer (ABC/MBC) in combination with an aromatase inhibitor (AI) as initial endocrine-based therapy in postmenopausal women or with fulvestrant in women with disease progression following endocrine therapy.³
- While clinical trials for palbociclib have evaluated patients’ health-related quality of life (HRQOL), few studies have explored the day-to-day and longitudinal effects of ABC/MBC and its treatment in a real-world setting.

OBJECTIVE

- Evaluate the engagement of patients with a peer-to-peer virtual patient community accessed via mobile application for patients receiving palbociclib in combination with an AI or fulvestrant per the product label within in a prospective multicenter study
- Evaluate the association between specific patient-reported HRQOL measures and activity based on level of engagement in the virtual community

METHODS

- As previously described,⁴ MADELINE is a multicenter study conducted in the US designed to evaluate patient-reported outcomes. The study enrolls women with ABC/MBC receiving one of the following treatments:
 - Palbociclib in combination with an AI as initial endocrine therapy or palbociclib in combination with fulvestrant after progression on prior endocrine therapy according to the Food and Drug Administration–approved indication for palbociclib
 - Approved therapies for ABC/MBC other than palbociclib
- As part of the MADELINE study, patients receiving palbociclib had access to a study-specific virtual community to allow patients to engage in peer-level discussions and provide peer-to-peer support, as well as access to resources about palbociclib and ABC/MBC, including treatment management tips and videos of patients sharing their experiences.
 - The engagement of patients with the virtual community was assessed by assigning points based on actions completed while enrolled in the study:
 - 3 points per video view and discussion topic added
 - 2 points per comment and direct message
 - 1.5 points per “like” on a discussion or comment
 - 1 point per virtual community visit
 - 0.5 points per page view and profile update
 - Points were summed to produce a total score, and patients were classified as high (≥ 70 points), medium (40 to <70 points), or low (0 to < 40 points) engagers.
- Patients completed an end-of-study survey (EOS) to rate the virtual community’s value during treatment on a 5-point scale (ranging from strongly agree to strongly disagree) and selected the most beneficial virtual community aspects.
- Real-time patient-reported outcomes data were collected via a novel mobile application to assess patient functioning and HRQOL through daily, weekly, and planned monthly, cycle-based questionnaires for 6 months following enrollment. The administration of the planned monthly, cycle-based questionnaires was based on patient reporting of drug usage.
 - Patients were administered the 12-Item Short-Form Health Survey (SF-12) and the Center for Epidemiologic Studies Depression Scale (CES-D-10) at baseline and monthly for 6 cycles.
 - The SF-12 measures 8 health concepts (physical functioning, limitations due to physical health problems, bodily pain, general health, vitality, social functioning, limitations due to emotional problems, and mental health), which form physical component summary (PCS) and mental component summary (MCS) scores. Scale scores for component summary scores range from 0 to 100, with higher scores representing better health status.
 - The CES-D-10 is a 10-item, self-administered questionnaire assessing depression during the last week.⁵ The 10 items are rated on a 4-point scale (0 [less than 1 day] to 3 [5-7 days]) and summed to produce a total score, ranging from 0 to 30. A total score of 10 or more is considered indicative of depression.
- An interim analysis was conducted of those patients who had completed the study as of May 1, 2019.

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RESULTS

Site Characteristics

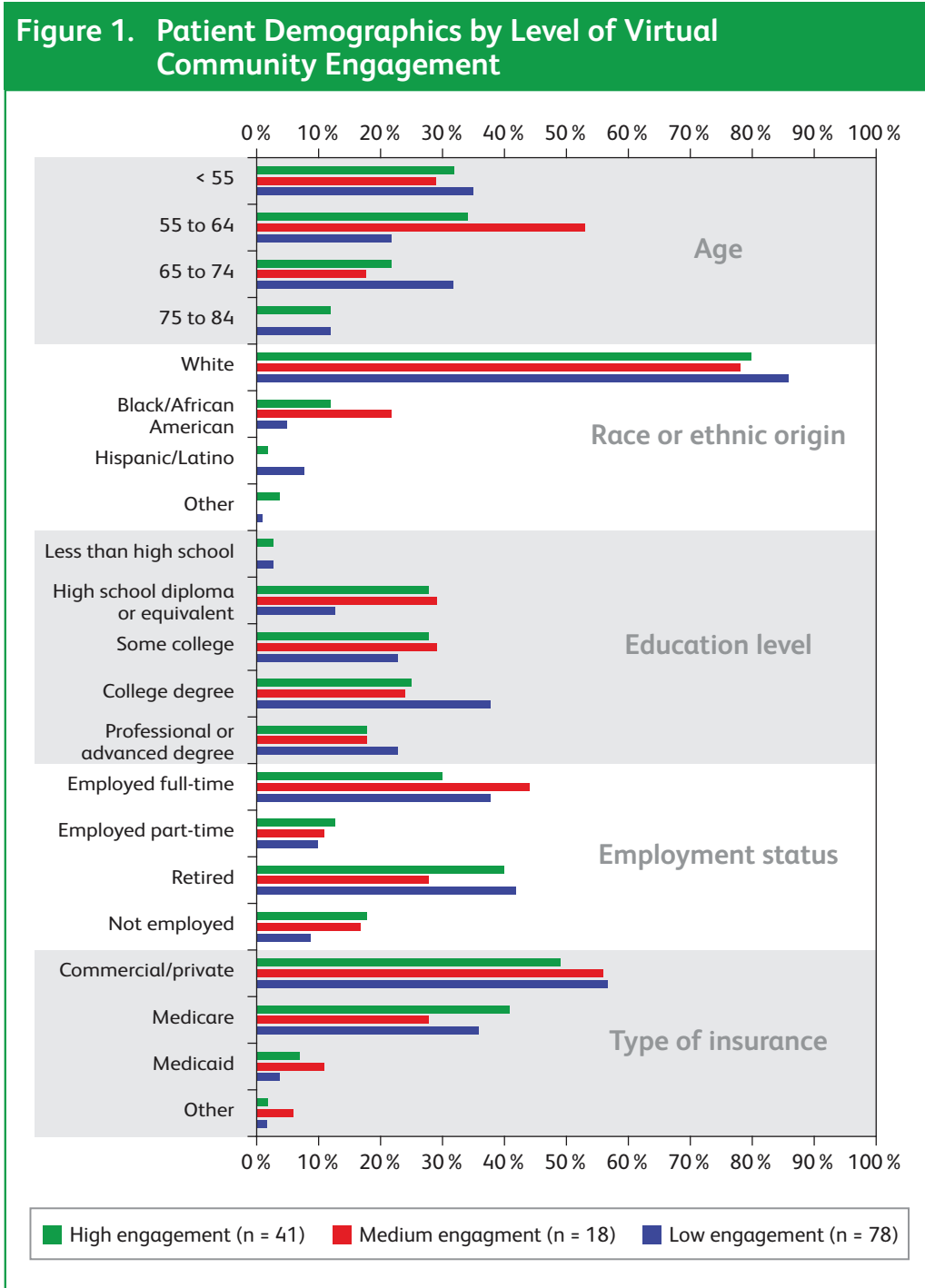
- 23 sites contributed 137 patients for this interim analysis. Sites were distributed across the US:
 - 48 % (11/23) were in the South, 22 % (5/23) were in in the Northeast, 22 % (5/23) were in the Midwest, and 9 % (2/23) were in the West.
 - 74 % (17/23) were community hospitals, and 26 % (6/23) were academic hospitals.

Patient Demographics

- The demographic profile was generally similar between the three virtual community engagement groups (Figure 1).

Engagement Within the Virtual Community

- Mean (minimum, maximum) community visits and page views, respectively, were 83 (17, 200) and 169 (39, 502) for high engagers, 19 (9, 31) and 52 (27, 88) for medium engagers, and 9 (1,24) and 16 (1,41) for low engagers (Figure 2).
- High engagers accounted for 88 % of discussion topics added (15/17), 81 % (96/119) of videos viewed in the virtual community, 80 % of direct messages (4/5), and 78 % (36/46) of comments (Figure 3).

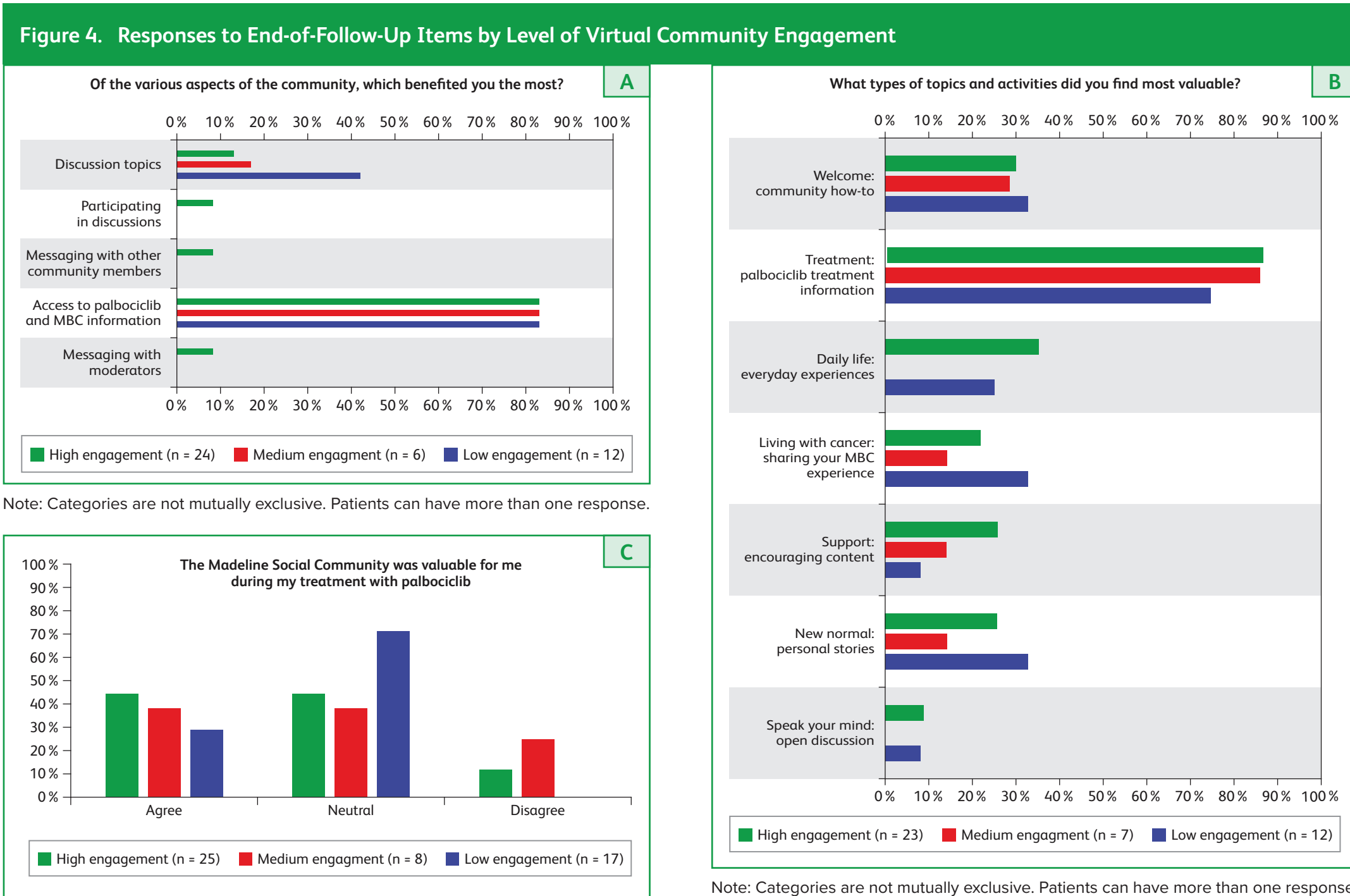
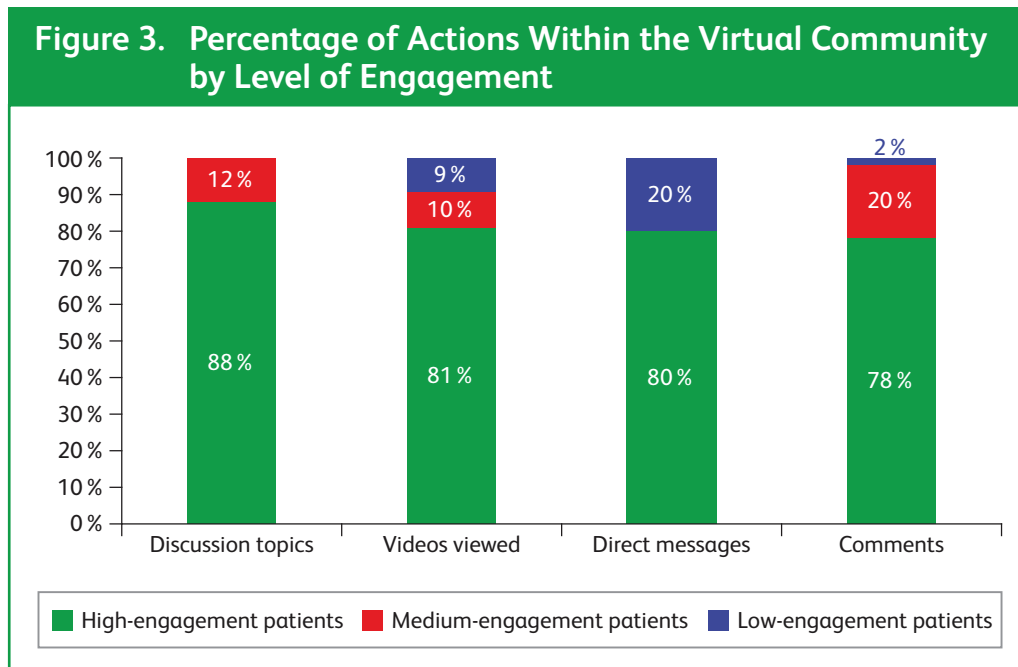
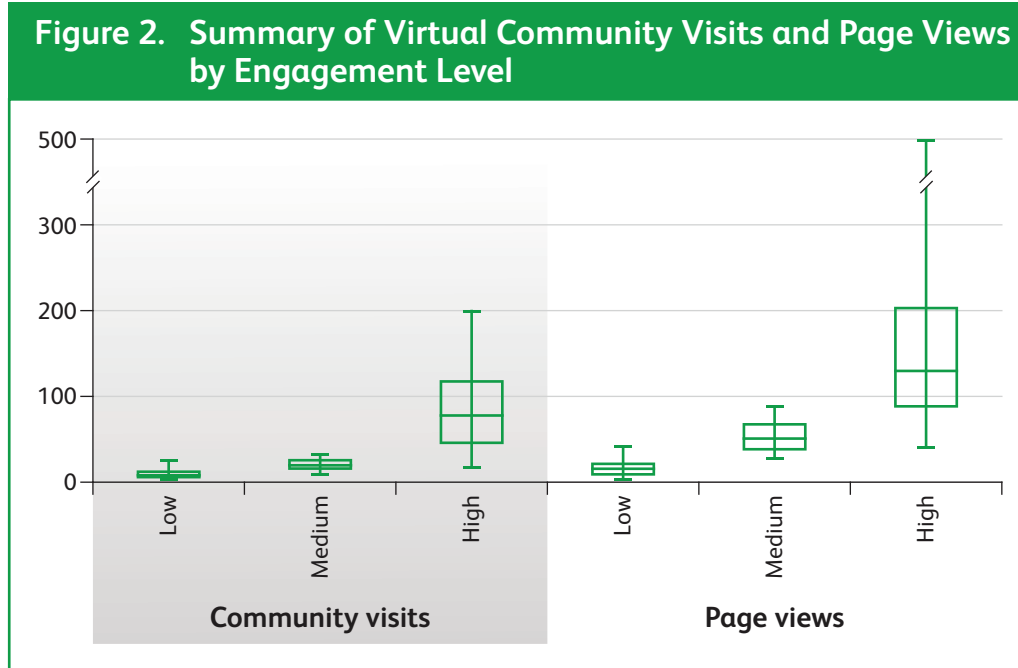


Value of the Virtual Community

- Figure 4 summarizes select end-of-follow-up items by engagement level. Eighty-three percent (35/42) of EOS respondents selected “Access to palbociclib and MBC information” as the most beneficial virtual community component and “Palbociclib treatment information” as the most valuable virtual community topic.
- 51 % (26/51) of EOS respondents indicated that they would like to participate in a social community of patients taking palbociclib if available outside the study.

Patient-Reported Outcomes by Virtual Community Engagement

- Mean (SD) SF-12 PCS change from baseline at cycle 1 for high (n = 25), medium (n = 6), and low (n = 41) virtual community engagers was –1.5 (4.85), –5.2 (6.33), and –2.4 (8.75), respectively.
- Mean (SD) SF-12 MCS change from baseline at cycle 1 for high (n = 25), medium (n = 6), and low (n = 41) virtual community engagers was 2.3 (6.73), 1.1 (7.31), and 0.4 (8.20), respectively.
- Mean (SD) CES-D-10 change from baseline at cycle 1 for high (n = 27), medium (n = 8), and low (n = 45) virtual community engagers was –0.4 (4.59), –1.0 (3.82), and 0.2 (3.89), respectively.



CONCLUSIONS

- The most frequent actions in the virtual community across all engagement groups were viewing information pages and patient videos, while the least frequent were posting discussion topics and sending direct messages.
- Patients found access to palbociclib and MBC information beneficial.
- SF-12 and CES-D scores remained relatively stable within engagement groups.

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