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RESEARCH ARTICLE

Communicating Alzheimer's biomarker results to cognitively unimpaired research participants: Satisfaction, utility, and impact on research attitudes

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Abstract

Introduction: Recruitment and retention pose a significant challenge to Alzheimer's disease (AD) research. Returning AD biomarker results to participants has been proposed as a means to improve recruitment and retention. We present findings related to participant satisfaction, utility, and impact on research attitudes from the amyloid positron emission tomography (PET) disclosure sub-study within the Wisconsin Registry for Alzheimer's Prevention (WRAP).

Methods: Ninety-nine cognitively unimpaired WRAP participants learned their amyloid PET results (mean age $\pm$ SD = 72.0 $\pm$ 4.8). Measures of reasons for wanting to learn results, study comprehension, result utility, visit satisfaction, research attitudes, and future study enrollment willingness were collected. Between-group, chi-squared analysis was conducted to determine differences by result type (elevated vs. not elevated amyloid PET result) in study comprehension, result utility, and visit satisfaction. Linear mixed-effects modeling was used to evaluate changes in research attitudes and enrollment willingness as a function of time, amyloid result type (elevated/not elevated), and their interaction.

Results: The reasons most frequently endorsed for wanting to learn amyloid PET result was a "desire to contribute to research on Alzheimer's disease dementia" and "to inform preventative measures [one] might take (e.g., change diet, exercise, or other lifestyle changes)." Overall, participants reported understanding the results and found learning them useful. Satisfaction with the study visits was overwhelmingly high, with over 80% agreeing with visit usefulness and their satisfaction. Few differences were found between participants who learned an elevated and not elevated result. Over the course of the study, participants who learned an elevated amyloid PET result reported higher willingness to enroll in drug trials (beta: 0.12, $p = 0.01$) and lifestyle interventions (beta: 0.10, $p = 0.02$) compared to participants who learned a not elevated result.

Discussion: Formal incorporation of disclosure practices may encourage participant recruitment and retention within AD research.

KEYWORDS
amyloid, disclosure, preclinical, recruitment, retention

Highlights

- Participants wanted to learn their amyloid results to contribute to research.
- Satisfaction with disclosure and post-disclosure visits was high overall.
- Returning AD biomarkers can increase willingness to participate in research.

1 | INTRODUCTION

Challenges in robust, representative recruitment to Alzheimer's disease (AD) research pose a critical barrier to continued advancement in disease understanding and treatment.[1] Many AD studies leverage biomarker testing, for eligibility screening in clinical trials, and tracking disease changes in observational studies. Historically, AD biomarker results have not been returned to cognitively unimpaired participants because results were not medically actionable, and experts worried results would be distressing.[2] Recent availability of disease-modifying treatments coupled with shifting attitudes toward bidirectional communication and transparency with research participants has driven a surge in return of individual AD biomarker results to research participants.[3]

Return, or disclosure, of AD biomarker results has been proposed to aid recruitment and retention, especially of individuals from underrepresented groups, within AD studies. In an interview study with 334 older adults, participants reported higher willingness to enroll in a biomarker study that included return of results than one that did not.[4] A study on longitudinal study retention found returning study results (including biomarkers) may encourage continued participation.[5] Return of results may even be an expectation, as demonstrated through interviews with older Black and Latino adults who reported they thought they should learn their positron emission tomography (PET) results as a part of study participation.[6] Importantly, learning results were a primary motivator for participation in AD PET scans. Collectively, these results emphasize the desire of research participants to learn their results and the important role disclosure can play in building positive research relationships.

Further, AD biomarker results are individually meaningful to cognitively unimpaired participants regardless of their clinical utility. Participants report wishing to receive AD biomarker results to better understand their brain health and risk of dementia.[6,7] Such information is personally actionable, with many participants citing making lifestyle changes to improve their health as an important reason for wanting to learn their AD biomarker results.[7] After learning AD biomarker or genetic test results, participants with results indicating an increased risk of AD dementia obtain long-term care insurance and think about or make AD-specific health behaviors at higher rates than those learning they are not at an increased risk of AD dementia.[8–10] Studies of disclosure also importantly demonstrate with adequate education participants understand their results and do not experience significant psychological distress.[2,11,12] However, it is important to note these studies were made up of predominantly White samples, so more research is needed using representative samples. There is also little evidence about the impact of disclosure on measures of study retention, research attitudes, and willingness to enroll in other studies exists.

In the Amyloid Disclosure Study[11] (ADS), a study of returning amyloid PET and dementia risk-reduction counseling in cognitively unimpaired older adults, we previously described the feasibility and safety of communicating amyloid PET results. This study focuses on providing initial findings related to how receiving different types of results may impact research attitudes and reported willingness to enroll in additional research studies. Here, we report reasons for wanting to learn amyloid PET results, feedback on various study elements, usefulness and satisfaction with study visits, and participant research relationships and attitudes. Together, these results may improve process design by providing information to increase the relevance of disclosure for participants and ensure participant needs are met within an AD biomarker disclosure protocol. Further, these results provide additional nuance to understand the impact of returning AD-related information to cognitively unimpaired individuals and may have relevance for how research studies manage and strengthen relationships with participants.[13] As more AD studies adopt disclosure practices, such considerations are increasingly relevant. Our aims are to describe participant perspectives on (1) reasons for learning amyloid PET results, (2) comprehension and utility of result, (3) satisfaction with disclosure and post-disclosure visits, and (4) effect of learning results on research attitudes and participation in AD-related research.

2 | METHODS

2.1 | Sample

A subset of participants were recruited from the Wisconsin Registry for Alzheimer's Prevention (WRAP),[14] a longitudinal observational research cohort, and enrolled in a sub-study focusing on the return

RESEARCH IN CONTEXT

1. **Systematic review**: The authors reviewed the literature using traditional (e.g., PubMed) sources. Currently published studies on the return of Alzheimer's disease (AD) biomarkers largely focus on participant safety, AD knowledge, and result understanding. There have not been published studies reporting the impact of returning AD biomarkers on research attitudes and willingness to enroll in future studies.
2. **Interpretation**: We demonstrate that study measures of study comprehension, result utility, visit satisfaction, research attitudes did not change across the study or vary by result type learned (elevated vs. non-elevated amyloid positron emission tomography [PET]). Over the course of the study, participants who learned an elevated amyloid PET result reported higher willingness to enroll in drug trials (beta: 0.12, $p = 0.01$) and lifestyle interventions (beta: 0.10, $p = 0.02$) compared to participants who learned a non-elevated result.
3. **Future directions**: Disclosure may be a mutually beneficial action. Participants can benefit by receiving the information they want, and studies can benefit through potentially increased participation.

of amyloid PET results to cognitively unimpaired participants.[11] Eligibility criteria included an amyloid PET scan within 18 months of study enrollment, aged 65 or older, no active Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnoses, and no consensus conference diagnosis of mild cognitive impairment (MCI) or dementia.[15,16] Further details on the sample can be found in Erickson et al. 2023.[11] Approval to conduct this human-subjects research was obtained by the University of Wisconsin-Madison Institutional Review Board.

2.2 | Consent statements

All participants provided informed consent to participate in the study. Study participation was voluntary. Participants could withdraw and elect not to learn their results at any time.

2.3 | Study design

The study included three visits (education session, amyloid PET disclosure, and dementia risk-reduction counseling) and three follow-up phone calls (1 to 3 days, 3 months, 6 months post-disclosure). Cross-sectional data included reasons for wanting to learn amyloid results, study visit satisfaction, and study comprehension and result utility. Longitudinal data included research attitudes and willingness and actual enrollment in additional research studies (Figure 1). All participants spoke English, and all visits were conducted in English. Additional psychological and behavioral outcomes were collected and described in more detail in Erickson et al. 2023.[11]

2.4 | Measures

2.4.1 | Reasons for wanting to learn amyloid results

We used the View and Perceptions of Amyloid Imaging scale[17] developed for the Anti-Amyloid Treatment in Asymptomatic Alzheimer's disease (A4) Study. We adapted the scale prompt to be about wanting to learn amyloid PET results because participants had already been scanned. The 10-item measure included ratings for how important each item was for learning results on a five-point scale from "not at all" to "extremely." This questionnaire was added after the study began and was completed by a subset of the total sample ($n = 69$).

2.4.2 | Study comprehension, result utility, and visit satisfaction

We developed five items to assess participant understanding and utility of amyloid results using a five-point scale from "strongly disagree" to "strongly agree." Items included helpfulness of educational materials, understanding of both amyloid results, usefulness of learning result, and regret.

Participants reported their satisfaction with the disclosure and dementia risk-reduction counseling visits. They answered two questions on a four-point scale from "not at all" to "very much" about the usefulness of and satisfaction with the visits. Participants provided visit feedback in open-ended questions and recommended if we should continue the visits.

2.4.3 | Research attitudes

Participants rated their agreement with the following items (1) "You have a positive view about the WRAP study" and (2) "The WRAP research team can be trusted to protect your interests and the interests of people who volunteer to take part in WRAP studies" on a five-point scale from "strongly disagree" to "strongly agree." Participants also completed the validated seven-item Research Attitudes Questionnaire[18] (RAQ-7).

2.4.4 | Willingness and actual enrollment in additional research studies

Participants rated their willingness to participate in different types of studies on a five-point scale from "not at all" to "extremely."

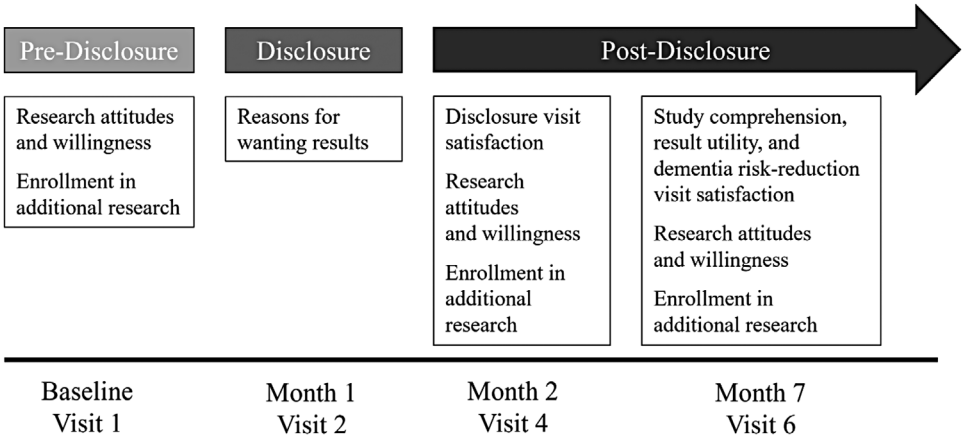

FIGURE 1 Visit flow with measures collected.

Probed studies included "research on Alzheimer's," "future drug trials" "lifestyle interventions (like exercise or diet)," and "(continued participation) in long-term studies, like WRAP."

At the end of the study, participants reported if they had enrolled in any other studies, including within WRAP, the University of Wisconsin-Madison, or elsewhere. They then selected the different study types they had enrolled in, which included options for "drug trial," "nondrug trial (e.g., improving exercise or diet study)," and "nontrial study (e.g., brain imaging, observational study including questionnaires or cognitive testing)." Participants could report enrolling in multiple additional studies.

2.5 | Statistical analysis

Descriptive statistics (percentages, means) were used to evaluate sample characteristics, reasons for wanting to learn results, study comprehension, result utility, visit satisfaction, and actual enrollment in other studies. Between-group, chi-squared analysis was conducted to determine differences by result type (elevated vs. not elevated amyloid) in study comprehension, result utility, and visit satisfaction.

Using linear mixed-effects modeling, we assessed relationships between our primary outcomes (relationship with WRAP [two items], RAQ-7 score, enrollment willingness [four items]), and predictors (visit number, amyloid result [elevated/not elevated], visit number x amyloid result interaction). Covariates included age, gender, and education. We centered all covariates and checked for variance inflation. We predicted attitudes toward WRAP specifically, and research generally RAQ-7 would remain positive across the study regardless of result type. We predicted after learning an "elevated" result, participants would report a higher willingness to participate in studies. Because the relationship with WRAP and enrollment willingness outcomes were discrete variables and may not be well-modeled with linear regression, we performed a sensitivity analysis using logistic regression models, dichotomizing the outcome variable as agree/disagree or willing/unwilling, respectively. All analyses were conducted using R Version 4.2.1,[19] with the LME4 package being used to conduct the linear mixed-effects modeling.[20]

3 | RESULTS

3.1 | Sample characteristics

The final sample included 99 participants (mean age ± SD = 72.0 ± 4.8; Table 1) and was predominantly female (66.7%), college-educated (69.4%), White (94.9%), and with a family history of dementia (64.6%). There were no significant demographic differences by amyloid results (elevated $n = 28$, 28.3%) (not elevated $n = 71$, 71.7%).

3.2 | Reasons for wanting to learn amyloid results

The reason most frequently endorsed for wanting to learn amyloid results was a "desire to contribute to research on Alzheimer's disease dementia." Eighty-seven percent of participants reported this was a very or extremely important reason. In rank order, the following reasons were reported as being very or extremely important, to inform preventative measures like behavior change (76.8%), to be able to participate in clinical trials (69.6%), to know more about the risk of developing AD dementia (63.8%), curiosity (58.0%), to put their mind at ease if they received a not elevated result (56.5%), to arrange personal affairs (50.7%), to prepare family for possible future illness (46.4%), and last, to confirm the feeling they are already developing symptoms of AD dementia (27.5%).

3.3 | Study comprehension, result utility, and visit satisfaction

Overall, about 79% of participants agreed or strongly agreed the educational materials were useful. Ninety-five percent agreed or strongly agreed they understood the meaning of the elevated and not

TABLE 1 Sample characteristics

Parameter	Overall	Amyloid not elevated	Amyloid elevated
Sample size (*n*)	99	71	28
Age	72.0 ± 4.8	72.3 ± 5.1	71.1 ± 4.0
Sex (*n* female, %)	66 (66.7%)	49 (69.0%)	17 (60.7%)
Education (*n* w/ ≥ Bachelor's, %)	68 (69.4%)	48 (67.6%)	20 (71.4%)
Self-identified race (*n*, %)	1 (1.0%) Asian 4 (4.0%) Black or African American 94 (94.9%) White	1 (1.4%) Asian 1 (1.4%) Black or African American 69 (97.2%) White	0 (0%) Asian 3 (10.7%) Black or African American 25 (89.3%) White
Family history of dementia (*n*, % yes)	64 (64.6%)	44 (62.0%)	20 (71.4%)

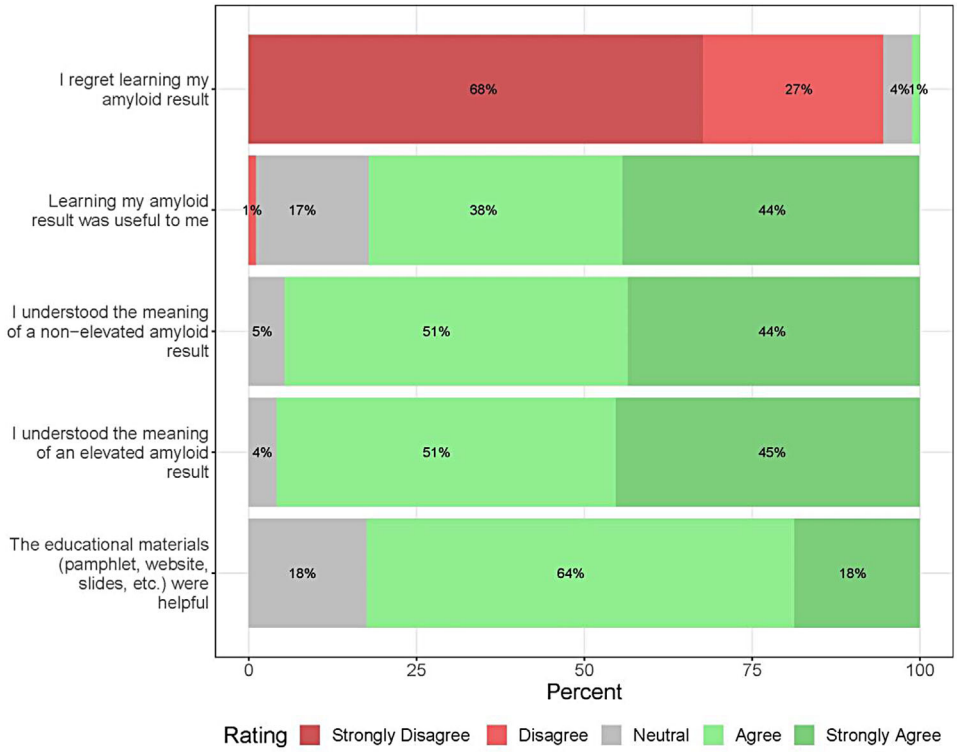

FIGURE 2 Response distributions for study comprehension measures.

elevated results. Eighty-two percent agreed or strongly agreed learning their result was useful. One participant reported regretting learning their results and they had learned a not elevated result (93% reported they disagreed or strongly disagreed regretting learning their results) (Figure 2).

There were no group differences in result understanding ($p = .98$) or result usefulness ($p = 0.47$) (Figure 2) (Supplemental Material includes item-level response distributions by amyloid result). Reported educational material usefulness did differ by amyloid result ($\chi^2 = 6.42$, df = 2, $p = 0.04$), with more elevated participants reporting they agreed or strongly agreed with the usefulness of the educational materials than not elevated participants (96% vs. 72%). There were also group differences in regret in learning results ($\chi^2 = 10.7$, df = 2, $p = 0.005$). Participants who learned an elevated result responded "neutral" more to the regret item than not elevated participants (15% vs. 0%). Further, not elevated participants responded "strongly disagree" more to the regret item than elevated participants (74% vs. 54%).

Overall, 95% reported the disclosure visit was "somewhat" or "very" useful (Figure 3). All participants recommended we continue the disclosure visits. Seventy percent reported the dementia risk-reduction counseling visit was "somewhat" or "very" useful. Eighty-one percent recommended we continue these visits. No statistically significant

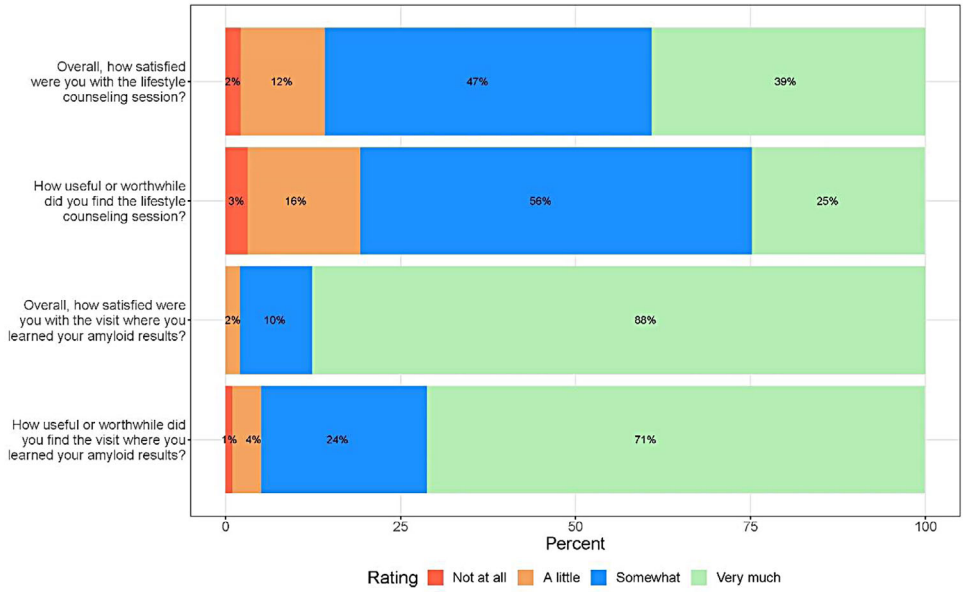

FIGURE 3 Response distributions for study visit satisfaction.

differences in either the disclosure or counseling visit's usefulness or satisfaction were found between participants with an elevated and not elevated result (Figure 3). Recommendations for the disclosure visit included more information on the amyloid result (e.g., provide scans, risk estimates, etc.), offering an in-person, face-to-face visit, and reducing the number of questions assessing suicidal ideation. Elevated participants, in particular, suggested allowing a loved one to join the visit. Recommendations for the counseling visit included more accountability check-ins and a more personalized discussion (including incorporating individual's identities, current lifestyle, and motivation and reviewing the purpose and goals of the visit).

3.4 | Research attitudes

All but one participant agreed or strongly agreed they had a positive view and trusted WRAP pre-disclosure and post-disclosure. Measures of the participant's views of WRAP did not differ over the course of the study ($p = 0.13$) nor by amyloid result ($p = 0.37$) or their interaction ($p = 0.16$). The planned sensitivity analysis was not able to be conducted as no participants reported disagreement with the statements.

The average RAQ-7 score was about 30 (max: 35) for both elevated and not elevated participants throughout the study. The visit was a significant predictor of RAQ-7 with scores 0.25 points lower with each successive study visit (beta: -0.25, $p = 0.004$). Amyloid result and the interaction of visit by amyloid result were both nonsignificant predictors ($p = 0.37$ and $p = 0.72$, respectively). Gender and education were significant predictors of RAQ-7 scores with women on average reporting scores 1.56 points higher than men ($p = 0.02$), and more years of education associated with higher RAQ-7 scores (beta: 0.26, $p = 0.05$). A table with full statistical parameters on these analyses is included in the Supplemental Materials.

3.5 | Willingness and actual enrollment in additional research studies

Visit ($p = 0.48$), amyloid result ($p = 0.52$), and their interaction ($p = 0.58$) were all nonsignificant predictors of willingness to enroll/continue in long-term studies. Only visit was a significant predictor of willingness to "contribute to research on Alzheimer's," with decreases in willingness with each subsequent visit (beta: -0.07, $p = 0.001$). Visit by amyloid result was a significant predictor of willingness to participate in future drug trials (beta: 0.12, $p = 0.01$). After learning their results, elevated participants reported greater willingness to enroll than participants who learned a not elevated result (Figure 4). This result was also seen in the lifestyle intervention item. Visit by amyloid result was a significant predictor of willingness to participate in lifestyle interventions (beta: 0.10, $p = 0.02$), with elevated participants reporting greater willingness to enroll than not elevated participants post-disclosure (Figure 4). Education was also a significant predictor of lifestyle intervention study enrollment willingness (beta = 0.08, $p = 0.02$). The strength and direction of the relationships modeled in the logistic regression sensitivity analyses were similar to the linear mixed effects regression results.

Thirty participants (30.9%) reported enrolling in other research studies since enrollment in the Amyloid Disclosure Study. Reported new enrollment did not differ by amyloid result ($\chi^2 = 0.25225$, df = 1, p-value = 0.6155). Two participants reported enrolling in drug trials (both received elevated result); 11 reported enrolling in a nondrug trial (e.g., for improving exercise or diet) (3 elevated, 8 not elevated); and 18 reported enrolling in nontrial studies (e.g. brain imaging, observational study including questionnaires or cognitive testing) (4 elevated, 14 not

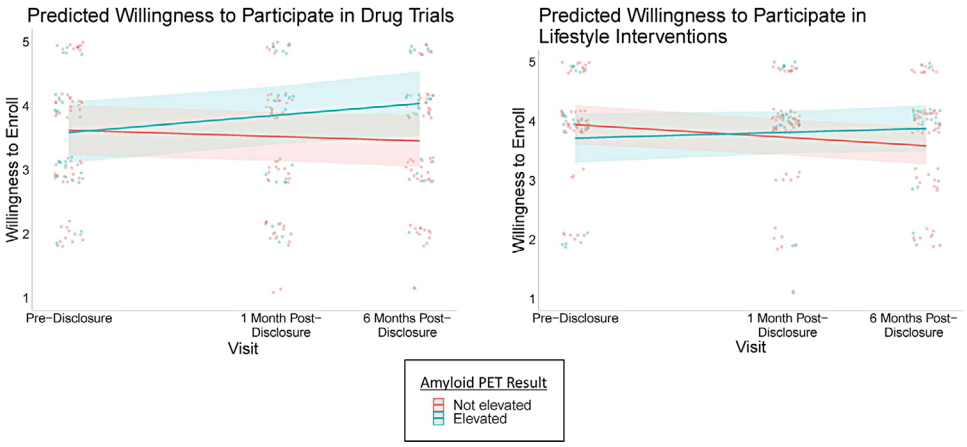

FIGURE 4 Plots for longitudinal reported willingness to enroll in drug trials and lifestyle interventions.

elevated). A table with full statistical parameters on these analyses is included in the Supplemental Materials.

4 | DISCUSSION

We aimed to describe participant perspectives on (1) reasons for learning amyloid PET results, (2) comprehension and utility of results, (3) satisfaction with disclosure and post-disclosure visits, and (4) effect of learning results on research attitudes and participation in AD-related research. The most commonly endorsed reasons for learning results included (1) wanting to contribute to AD research, (2) using the results to inform preventative measures for AD, including behavior changes, and (3) being able to participate in clinical trials. These findings recapitulate those from Ryan et al. 2021[17] which found at the beginning of the study (prior to imaging and disclosure) that the "Plan/Prepare" and "Altruism/Contribute" categories of items had the highest scores. Collectively, these results suggest participants' desire to learn their results to contribute more to research. Disclosure may thus be a mutually beneficial action. Participants can benefit by receiving information they want (with necessary supports to understand this information) and studies can benefit through potentially increased participation.

Importantly, neither understanding of results nor usefulness of learning the result differed by amyloid result, suggesting disclosure can be useful regardless of the result learned. Further, only one participant reported regretting learning their result, and they had received a not elevated result. A majority of participants found the disclosure and dementia risk-reduction counseling visits useful and recommended they continue to be offered, though participants more strongly endorsed the disclosure visit. We speculate participants were most interested in receiving their results and so found the dementia risk-reduction counseling visit to be less relevant. Similar to other studies,[10] participants desired more information about their results, including risk estimates and seeing their scans. Elevated participants, in particular, offered that in the future we should allow loved ones to join the visit. This highlights the need for additional support and begets thought about how loved ones might be affected by learning this information, taking on a pre-caregiver type role.[21]

Attitudes toward the observational cohort study (WRAP) and medical research more broadly (as assessed by the RAQ-7), unsurprisingly started and remained strongly positive throughout the duration of the study, suggesting while disclosure did not improve research attitudes; it maintained already positive ones. Though as prior research demonstrates, research attitudes are largely related to years of formal education so the inclusion of people with less formal education is needed to understand how disclosure may impact their attitudes toward medical research. The finding is still of particular interest when considering participants did not receive clear risk estimates. Though we only returned a binary amyloid result in which implications for individual risk were not well-defined, participants still expressed goodwill toward research, meaning amyloid result disclosure did not harm participant's relationship with WRAP or attitudes toward medical research in general. For Alzheimer's Disease Research Centers (ADRC) and observational cohorts, these results offer preliminary encouragement to adopt formal practices of returning AD risk information. Though we are limited by the design of the study at present, future studies may investigate how disclosure and research attitudes may play a role in study recruitment and retention. This may include comparing research attitudes, willingness, and retention between participants who receive their results with a control group who do not have the opportunity or who opt-out of receiving results.

We did find modest decreases in willingness to participate in Alzheimer's research over the course of the study for the total sample. We believe this small decrease in willingness may reflect study fatigue from participation in this study. This was a relatively intensive study with a number of questionnaires over about 9 months of participation. Near the completion of the study, participants may have desired a break from studies that seemed burdensome without the perceived potential benefit of a clinical trial. Interestingly, willingness to participate or continue participating in long-term studies, like WRAP, did not change over the course of the study, suggesting participants were still willing to participate in WRAP but perhaps not take on new Alzheimer's research opportunities.

Of note, willingness to enroll both in future drug trials and lifestyle interventions showed a statistically significant increase over the study for participants who learned an elevated amyloid PET result. It is possible that people's perceived risk increased their willingness to engage in studies focused on treating AD or reducing risk for the disease. Disclosure of elevated results may bolster willingness to participate in interventional research. This supports prior research[7–10] suggesting individuals seek action after learning they have elevated amyloid, such as making changes to their daily life, planning for the future, and as demonstrated here, possibly desiring to get involved in studies targeting disease intervention.

Identifying limitations is necessary to contextualize our findings. First and foremost, the sample was homogenous, largely made up of non-Hispanic White, college-educated women. These key limitations hinder the generalizability of our findings. Incidence and prevalence of AD and dementia are higher among Black and African American, Hispanic and Latino/e, and Indigenous communities, though are most often underrepresented in AD and dementia research. As disclosure practices expand in research and clinical settings, it is absolutely essential we understand (1) how to communicate AD biomarker information in culturally informed and accessible ways and (2) the broader experience of learning this information by people not currently reflected in studies of disclosure. Second, the sample was enrolled from an existing longitudinal, observational study. Participants had extensive experience with research and knowledge/exposure to AD science and terminology. This also presents an opportunity for future research to explore how the length of study enrollment may be related to research altruism and willingness to enroll in future AD studies. Finally, the protocol used for this study was resource-intensive for study staff and participants, potentially making it difficult to replicate in other studies or in clinical practice.

Numerous avenues exist for future studies to expand the science of AD biomarker disclosure including more direct assessment of the relationship between disclosure and study recruitment and retention and focusing on more representative samples (e.g., racial and ethnic minorities, people with less formal education, etc.). Implementation of more pragmatic approaches for AD biomarker disclosure that may be scalable for large studies and clinical settings is necessary as we prepare for a quickly approaching future in which many more people may receive AD biomarker testing and disclosure. While the practice of disclosing AD biomarkers increases, it is important to maintain approaches centering on the experiences of people learning this personal and sensitive information about themselves. Our participant feedback suggests future studies should include more information about the amyloid result (e.g., provide scans, risk estimates), options for in-person, face-to-face visits, and allowing a loved one to join visits. We believe findings from our study on participant perspectives can help inform approaches to increase comprehension and readiness and improve the participant and patient experience.

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CONFLICT OF INTEREST STATEMENT

C.M.E., F.B.K., K.E.B., N.A.C., M.L.E., and L.R.C. report no relevant conflicts of interest to disclose. Author disclosures are available in the supporting information.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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