


Final Report

PROTOCOL TITLE:	IMPROVING QUALITY OF LIFE FOR PEOPLE OVER 65 LIVING WITH DEMENTIA <i>A randomized controlled pilot study of using a personalized memory game app to improve the quality of life of people over 65 living with dementia and their carer(s)</i>	
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1 Executive Summary

This was a pilot study aimed at identifying whether use of the Memory Lane Games app, in particular the individualised version, was associated with any changes in quality of life (QoL) of persons with dementia (PWD) and/or their main carers. In addition, impacts on communication and any unanticipated effects were examined. The methodology was scrutinised for its suitability in a larger, future trial.

An open invitation was extended to residents of the Isle of Man via the media and community organisations. Participants had to be diagnosed with mild/moderate dementia, 65 years of age or over and not suffering from severe depression. Twelve pairs of PWD plus carer were recruited and data was collected by questionnaire and interview at baseline, week 13 and week 26. The questionnaires used were the MMSE, the CDR, the DEMQOL, the C-DEMQOL and the Holden Communication Scale (HCS). Data collection was completed in November 2022.

The results must be viewed in light of the small sample size but we have summarized here some of the main findings, which are mixed.

Intervention participants showed a small decrease in their median CDEMQOL score at week 26 but a slight increase in their median DEMQOL score. Control participants showed a slight increase in their median CDEMQOL score by week 26 while there was a large drop in median DEMQOL score. Participants with high adherence to playing the app over the study period show a moderate decrease in their median CDEMQOL score, but a similar level of increase in the DEMQOL scores. However, participants with low adherence exhibit a small decrease in both CDEMQOL and DEMQOL scores.

Participants with a positive sentiment towards the app in the qualitative data exhibited a moderate decrease in median DEMQOL scores by week 26 but a small increase in CDEMQOL scores. No-one had a negative sentiment but those who were neutral had a moderate increase in DEMQOL scores and a small decrease in CDEMQOL scores.

Participants who felt the app had impacted their communication positively showed a small increase in the median CDEMQOL scores but a moderate decrease in DEMQOL score. Those who felt the app had not impacted communication showed a moderate decrease in both CDEMQOL and DEMQOL scores.

Those participants who played a higher number of games per week showed a moderate drop in median CDEMQOL score but there was a large drop in CDEMQOL score for those who played a low number of games. Despite this decline in carer QoL among those who used the app consistently, 66% of carers believed that the time spent using the app was worthwhile, with 2 of them finding it very

worthwhile and 33% of carers reported that the app had a positive impact on the PWD's thinking abilities. Communication was a common theme that emerged in the semi-structured interviews, and 42% of carers believed that the app had helped them communicate more with their loved one, 58% believed it had helped the PWD communicate more and none of the carers reported that the app had led to a decrease in communication.

This pilot study has generated a lot of preliminary data which raises interesting hypotheses for further study. The questionnaires used in the study proved useful for this group of participants. Many comments were obtained which could help to improve the app and its functions and also perhaps target it at those most likely to benefit.

2 Results

2.1 Sample characteristics

Table 1 summarises the demographics and characteristics of the study sample. Listing of the data is not included due to the small sample which may render participants identifiable.

A sensitivity analysis was performed to assess the potential impact of individual participants on the overall results. After careful consideration, it was determined that the personal circumstances of a particular participant and their carer had significantly changed during the study period and this was likely to have a significant effect on the quality of life and communication outcome measures (CDEMQL, DEMQL, and HCS). As a result, this participant was removed from most of the analyses.

Variable	PWD (n)	Carer (n)
Treatment		
Intervention	8	8
Control	4	4
Sex		
Male	8	2
Female	4	10
Age		
<60	0	5
61-70	1	3
71-80	6	3
≥81	5	1
Years diagnosed		
<2	8	
≥2	4	
Diagnosis		
Dementia	3	
Vascular Dementia	4	
Lewy Body	1	
Alzheimer's	3	
Mixed Dementia	1	
Cohabit?		
Yes	7	
No	5	

Table 1. Sample demographics and characteristics summary (this includes all participants)

2.2 CDR and SMMSE categorisations

As the two dementia ratings used different categorisations, severity categorisations were normalised. Ultimately SMMSE scores were used to determine severity throughout the study and to determine participant eligibility.

SMMSE Categorisations	
Score	Category
30-	Maybe
25	normal
24-	Mild /
21	Early
21-	Moderate
10	
9-0	Severe

Table 2. Original SMMSE dementia categorisations (Malloy & Clarnette, 1999)

CDR Categorisations	
Score	Category
0	None
0.5	Questionable
1	Mild
2	Moderate
3	Severe

Table 3. Original CDR categorisations (Schmidt, 2014)

Study Categorisations		
Category	CDR score	SMMSE score
Questionable	0.5	30-25
Mild	1	24-20
Moderate	2	19-10
Severe	3	9-0

Table 4. Normalised dementia severity categorisations.

2.3 CDR and SMMSE comparisons

The SMMSE categories can be seen in Table 5. Categorisations remained the same at the end of the study period in 75% of cases. In 17% of cases the severity of dementia reduced and in 8% of cases it increased. It is widely reported that dementia severity scores can fluctuate over time (Lee, Taylor, & Thomas, 2012; Sun et al., 2017; Trachsel, Hermann, & Biller-Andorno, 2014). This is the most likely cause of a noted reduction in severity from baseline to week 26 for two participants.

SMMSE Baseline	SMMSE Week 26
Mild	Mild
Moderate	Moderate
Mild	Mild
Moderate	Moderate
Moderate	Moderate
Moderate	Moderate
Mild	Mild
Mild	Mild
Mild	Questionable
Moderate	Mild
Mild	Moderate
Moderate	Moderate

Table 5. SMMSE categorisation comparisons from baseline to week 26

2.4 Holden Communication Scale (HCS) assessment scoring

HCS data was captured according to the assessment documentation. The raw data was edited to improve interpretation: the initial scale of 0-4, 0 being the best possible score and 4 being the worst, was changed to 4 as the best possible score and 0 the worst. Example question, answers and score change can be seen in Table 6.

Question	Response choices	Original Scoring	Altered scoring for analysis
Response	Initiates conversation deeply involved with anyone	0	4
	Fair response to those close by; no initiation of conversation	1	3
	Good for those familiar to person	2	2
	Rather confused; poor comprehension	3	1
	Rarely or never converses	4	0

Table 6. Example HCS question illustrating the original score scale and the altered scale used for analysis.

2.5 Holden Communication Scale (HCS) variables

After review of the HCS score it was deemed that the 'Awareness and Knowledge' section of the assessment was probably not relevant to the research question. We therefore removed the 'Awareness and Knowledge' section score from the overall HCS score. This new outcome variable is referred to as 'Overall HCS (no awareness)' for the remainder of the report. The questions which were removed from this variable are in Table 7.

A: Original HCS categories		
Conversation	Awareness and Knowledge	Communication
Response	Names	Speech
Interest in past events	General orientation	Attempts at communication
Pleasure	General knowledge	Interest and response to objects
Humour	Ability to join in games	Success in communication

B: Altered HCS categories	
Conversation	Communication
Response	Speech
Interest in past events	Attempts at communication
Pleasure	Interest and response to objects
Humour	Success in communication

Table 7. A – Original HCS categories which are represented by the 'Overall HCS' variable. B – Altered HCS categories with awareness and knowledge removed from the data, represented by the 'Overall HCS (no awareness)' variable. Both variables are analysed throughout the report.

2.6 Variables used to create groups for analysis

Other than control and intervention groups, we explored several variables to group participants and examined outcome data. This included groupings relating to the use of the App, perceptions of the App and characteristics of the PWD or carer. Grouping variables were derived from qualitative data: they were derived independently by two researchers and compared (no discrepancies occurred). All grouping variables are described in Table 8. Additional variables were explored during the interim analysis but are not included in this report because they did not appear to add anything to the findings.

Variable	Group 1 (n)	Group 2 (n)	Group 3 (n)	Comments
Application allocation	Control (3)	Intervention (8)		
Dementia Severity	Mild (8)	Moderate (3)		The normalized SMMSE categories were used to categorise the Mild and Moderate groups for analysis
Adherence 75%	Low (7)	High (4)		Adherence is defined as the percentage of weeks that at least one game was played out of the 13 weeks.
General sentiment towards app	Neutral (3)	Positive (8)		Those who played for 75% or more of the weeks were defined as 'high adherence'. Those who played for less than 75% of the weeks were defined as 'low adherence'. General sentiment was deduced by analysing the week 13 interviews. Language and specific answers to questions were used to assign each participant into the negative, neutral, and positive groups. (0 participants had a negative sentiment).
Communication/Relationship sentiment	Neutral (8)	Positive (3)	Mixed (2)	Communication sentiment was deduced by analysing the week 13 interviews. Language used surrounding communication and PWD / carer interaction and answers to specific questions were used to assign each participant into the negative, neutral, and positive groups. (0 participants had a negative sentiment).
No. of games played	Low (8)	High (3)		The average total number of games played over the 13 weeks was calculated; any participant below or equal to the average was assigned as low and any participant higher than the average was assigned as high.

Table 8. List of each variable used to explore the data including. Each variables distinct groupings are listed along with explanations for variables in the comment's column when necessary. The participant who was removed from analysis is not included in these groups therefore the total number of participants in each variable is 11 not 12. Each group (n) references the number of participants that make up that group from baseline-week 13, any changes in number of participants within a group is discussed in section 2.8.2.

2.7 Effect of dementia severity on quality-of-life scores

Quality of life (QoL) is our main outcome measure and so we were interested in any association with dementia severity. Our findings showed a slight positive correlation between carer and PWD QoL and dementia severity (and Figure 2). As dementia becomes more severe, both carer and PWD QoL tend to decline. However, we found no consensus in previous research on whether dementia severity and QoL are directly correlated.

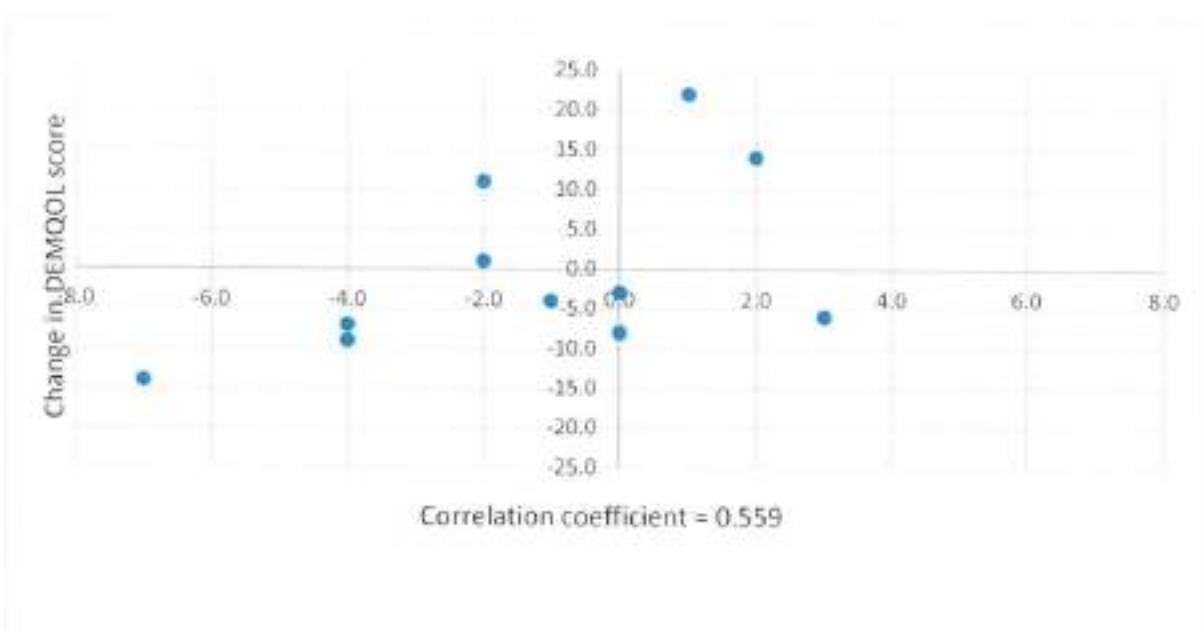


Figure 1. The change in DEMQOL scores compared to the change in SMMSE scores from baseline to week 26. 006 has been removed from analysis due to personal circumstances. 009 is not included as baseline DEMQOL was not recorded.

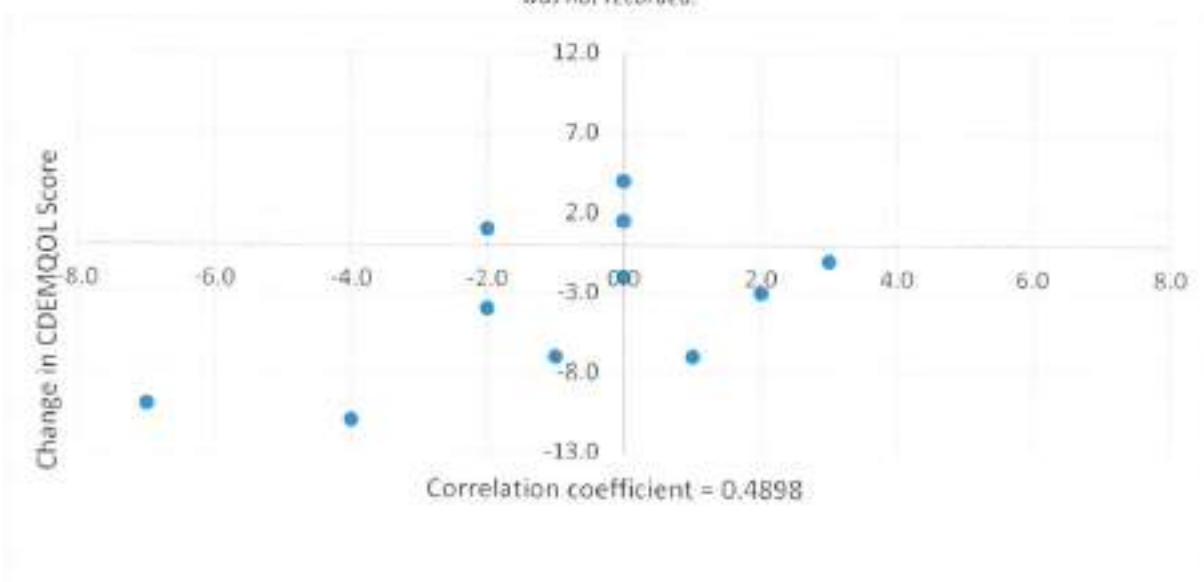


Figure 2. The change in CDEMQOL scores compared to the change in SMMSE scores from baseline to week 26. 006 has been removed from analysis due to personal circumstances.

2.8 Outcome Variables by each grouping

Due to the high variability in outcome variable scores, we used the median rather than the mean to examine the impact of group assignment on the outcome measures. The median is more robust when using data with significant variability while the mean is more sensitive to extreme values.

2.8.1 Usage trends:

Figure 3 indicates that usage among all participants tends to decrease in the latter half of the study (weeks 14-26). This could impact on consistency of impacts throughout the study period and should be considered when interpreting the results.

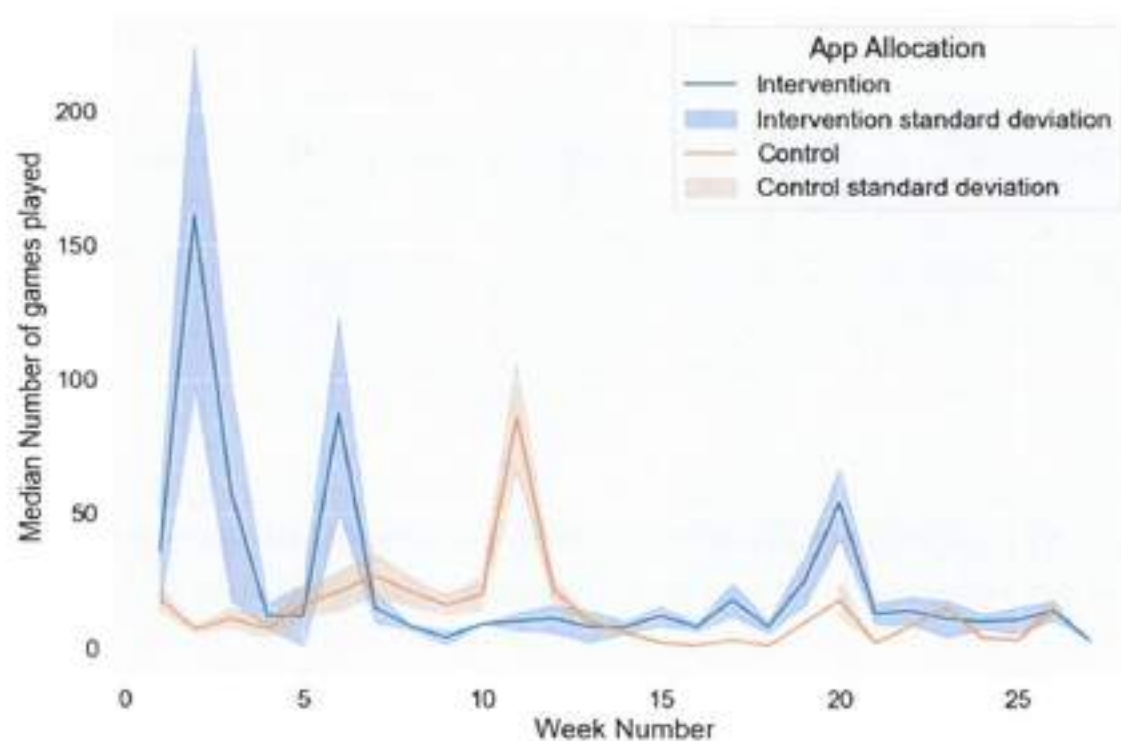


Figure 3. Median number of games played per week from week 1 -26. Participants grouped by app allocation.

2.8.2 Category Changes

2.8.2.1 Adherence changes

Adherence was measured as the number of weeks in which at least one game was played by the participant. We defined low adherence as less than 75% of the study weeks, and high adherence as 75% or more of the study weeks. Table 9 shows changes in adherence categorisation during the course of the study.

ID number	Week 13 Adherence	Week 26 Adherence
001	low	low
002	high	high
003	high	high
004	low	low
005	high	low
*006	high	low
007	low	low
008	high	low
009	low	low
010	low	low
011	low	low
012	low	low

Table 9. The adherence categories for each participant at week 13 and week 26. *006 is shown in this table however has been removed from the analysis and any conclusions drawn from the data.

2.8.2.2 Changes in number of games played

The 'number of games played' variable was created by, first, averaging the number of games played per week over all participants, which was 6, and then categorising those who played 6 or more games per week as high and the rest as low. Changes in categorisation can be seen in Table 10. The high categories at week 26 have a small sample size ($n=2$), so care needs to be taken when generalising to a larger population.

ID number	Week 13 Number of games played	Week 26 Number of games played
1	high	high
2	low	low
3	high	high
4	low	low
5	low	low
6	high	low
7	low	low
8	high	low
9	low	low
10	low	low
11	low	low
12	low	low

Table 10. The number of games played categories for each participant at week 13 and week 26. *006 is shown in this table however has been removed from the analysis and any conclusions drawn from the data.

2.8.3 Quality of life outcomes by group: Control versus intervention

A

Control participants show an initial drop at week 13 but an overall 1.5-point increase in median CDEMQL score by week 26. They also show a consistent drop at both time points amounting to -9-point decrease in median DEMQOL score at week 26. Intervention participants show an overall drop of -1.5 points in median CDEMQL score at week 26 but an increase in median DEMQOL score at week 13 which becomes a slight increase of 0.5 points at week 26.

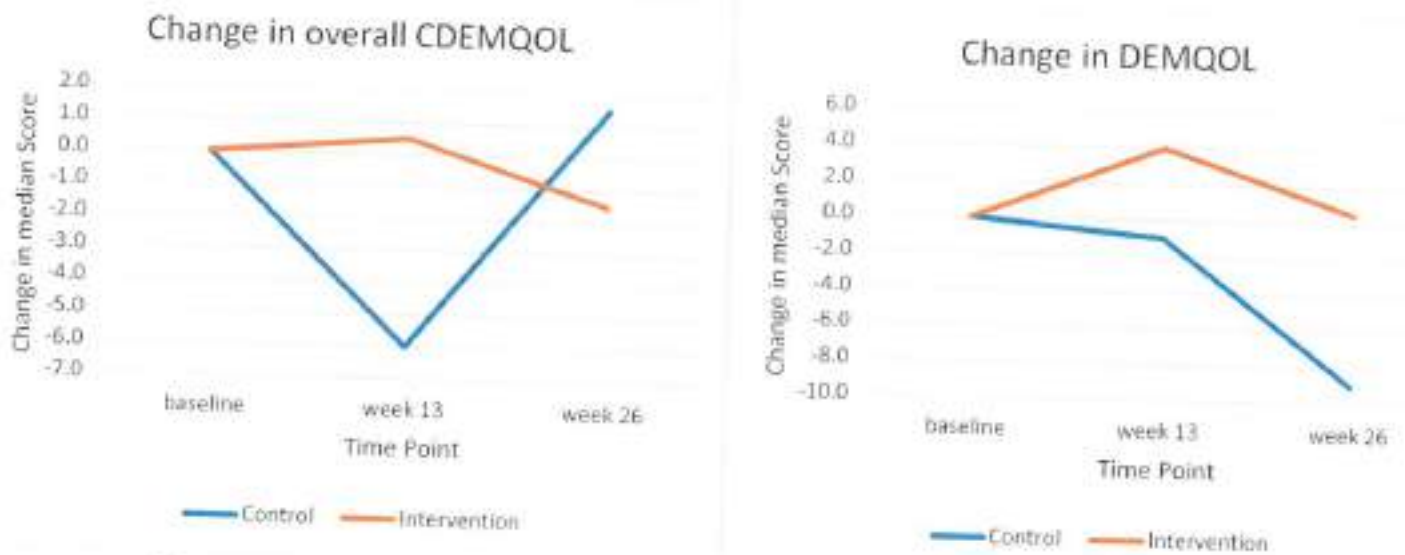


Figure 4. A – Change in median overall CDEMQL grouped by app allocation from baseline to week 26.

B – Change in median overall DEMQOL grouped by app allocation from baseline to week 26.

2.8.4 Quality of life outcomes by

group: Adherence 75%

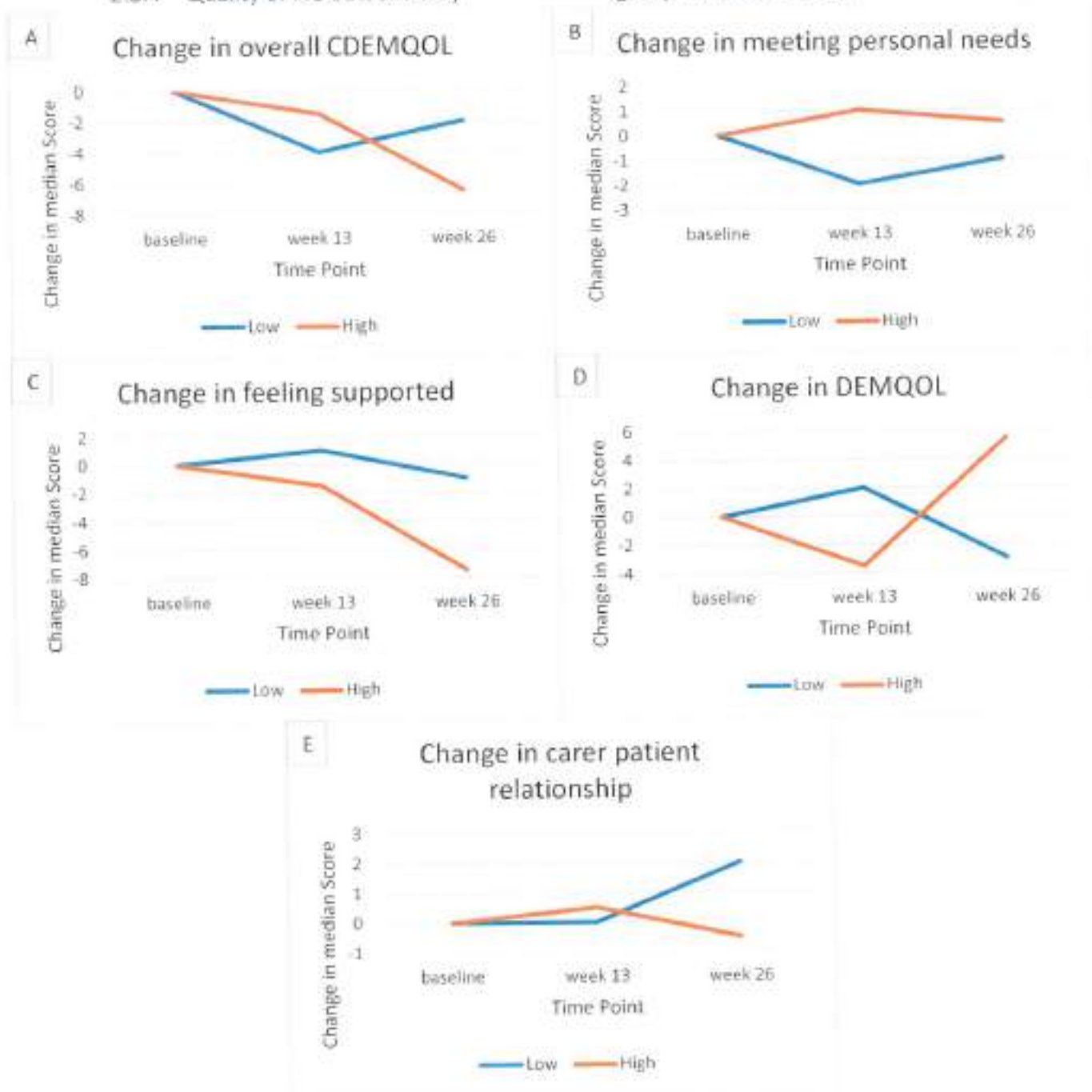
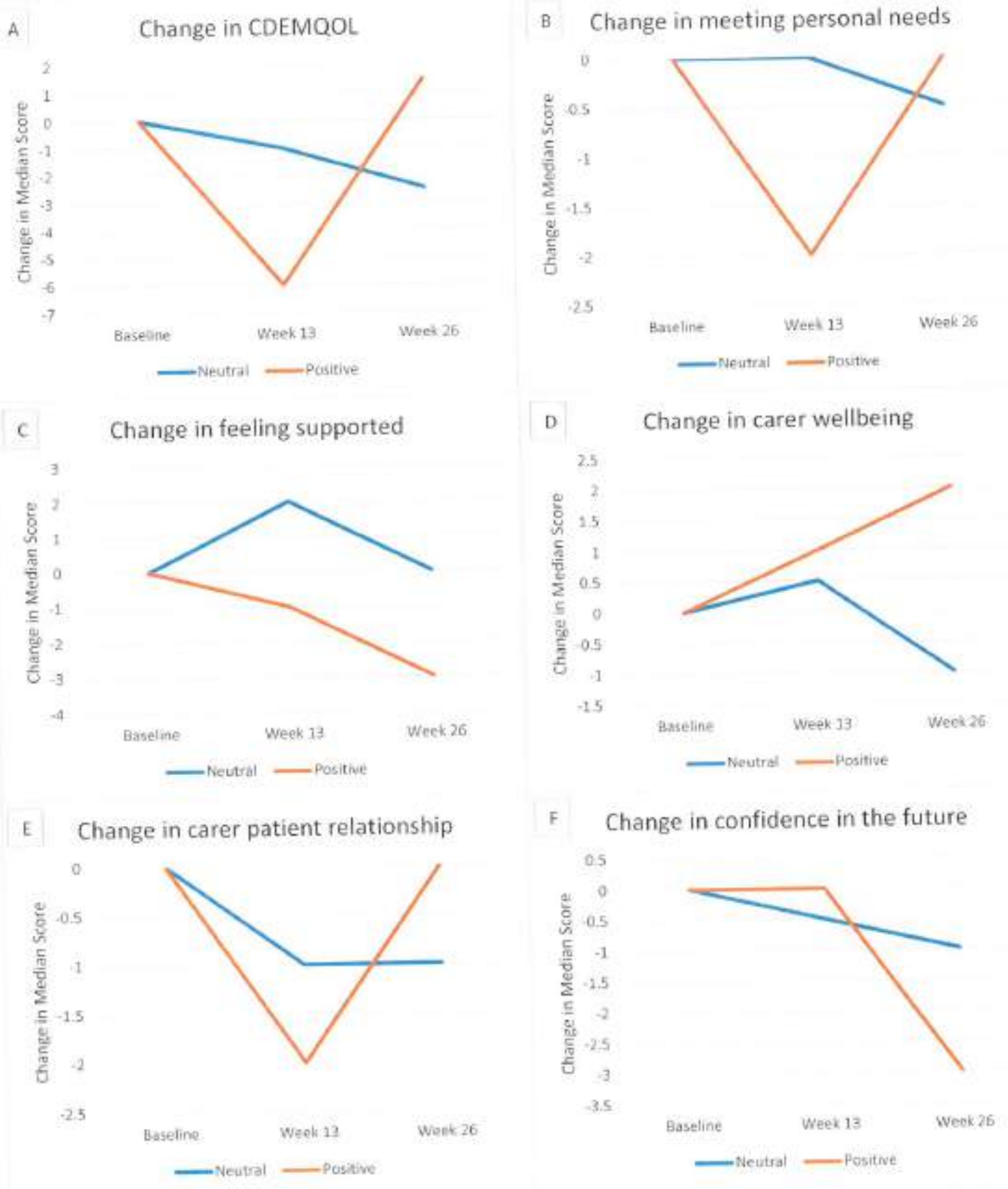


Figure 5. A – change in median overall CDEMQL grouped by adherence from baseline to week 26. B – change in median overall ‘meeting personal needs’ grouped by adherence from baseline to week 26. C – change in median overall ‘feeling supported’ grouped by adherence from baseline to week 26. D – change in median overall DEMQOL grouped by adherence from baseline to week 26. E – change in median ‘carer patient relationship’ grouped by adherence from baseline to week 26.

Participants with high adherence show a -6.5 decrease in median CDEMQL score, a -0.5 decrease in 'carer patient relationship' score, and a -7.5 decrease in 'feeling supported' score; they also exhibit an increase of 0.5 in 'meeting personal needs' scores and an increase of 5.5 in the DEMQL scores. Participants with low adherence exhibit a decrease in median CDEMQL scores (-2), 'meeting personal needs' scores (-1), 'feeling supported' scores (-1), and DEMQL scores (-3) from baseline to week 26. Participants with low adherence show an increase in median 'carer patient relationship' scores (-0.5) from baseline to week 26.

2.8.5 Quality of life outcomes by group: General sentiment towards app



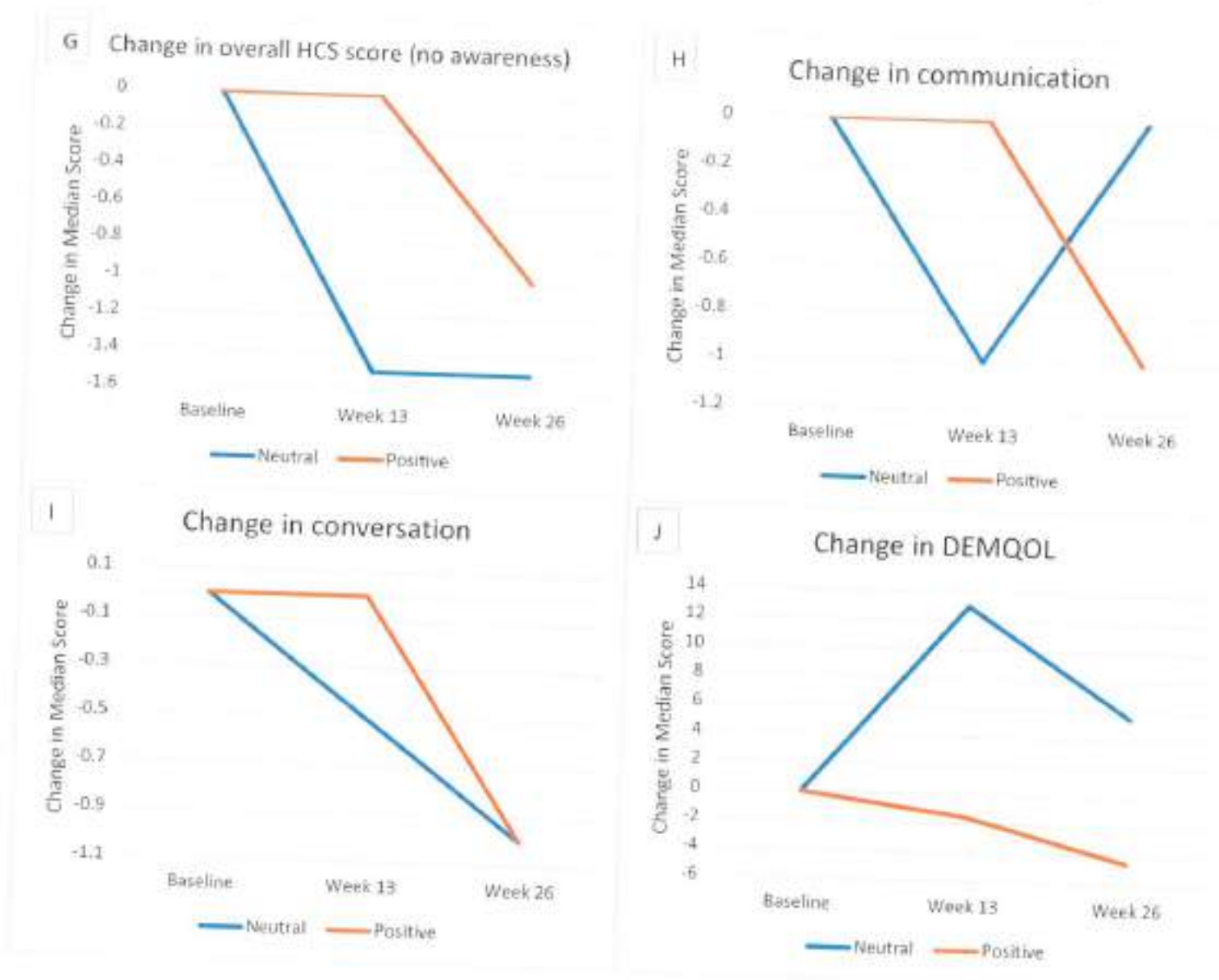


Figure 6. A – change in median overall CDEMQL grouped by sentiment towards app from baseline to week 26. B – change in median overall ‘meeting personal needs’ grouped by sentiment towards app from baseline to week 26. C – change in median overall ‘feeling supported’ grouped by sentiment towards app from baseline to week 26. D – change in median overall ‘carer wellbeing’ grouped by sentiment towards app from baseline to week 26. E – change in median overall ‘carer patient relationship’ grouped by sentiment towards app from baseline to week 26. F – change in median overall ‘confidence in the future’ grouped by sentiment towards app from baseline to week 26. G – change in median overall ‘HCS score (no awareness)’ grouped by sentiment towards app from baseline to week 26. H – change in median overall ‘communication’ grouped by sentiment towards app from baseline to week 26. I – change in median overall ‘conversation’ grouped by sentiment towards app from baseline to week 26. J – change in median overall DEMQOL grouped by sentiment towards the app from baseline to week 26.

Participants with a positive sentiment exhibited a decrease in median 'feeling supported' scores (-3), 'confidence in the future' scores (-3), 'overall HCS (no awareness)' scores (-1), 'communication' scores (-1), 'conversation' scores (-1), and DEMQOL scores (-4.5) from baseline to week 26. Those with a positive sentiment elicited an increase in median CDEMQOL scores (1.5) and 'carer wellbeing' scores (2) overtime. Individuals with a positive sentiment also tended to show no change in 'meeting personal needs' scores and 'carer patient relationship' scores from baseline to week 26.

Participants who had an overall neutral sentiment towards the app displayed a decrease in median CDEMQOL scores (-2.5), 'meeting personal needs' scores (-0.5), 'carer wellbeing' scores (-1), 'carer patient relationship' scores (-1), 'confidence in the future' scores (-1), overall HCS (no awareness) scores (-1.5), and 'conversation' scores (-1). Change in median DEMQOL scores increased by 5.5 in those who has a neutral sentiment towards the app, and no change was seen in 'feeling supported' and 'communication' scores.

2.8.6 Quality of life outcomes by group: Communication/relationship sentiment

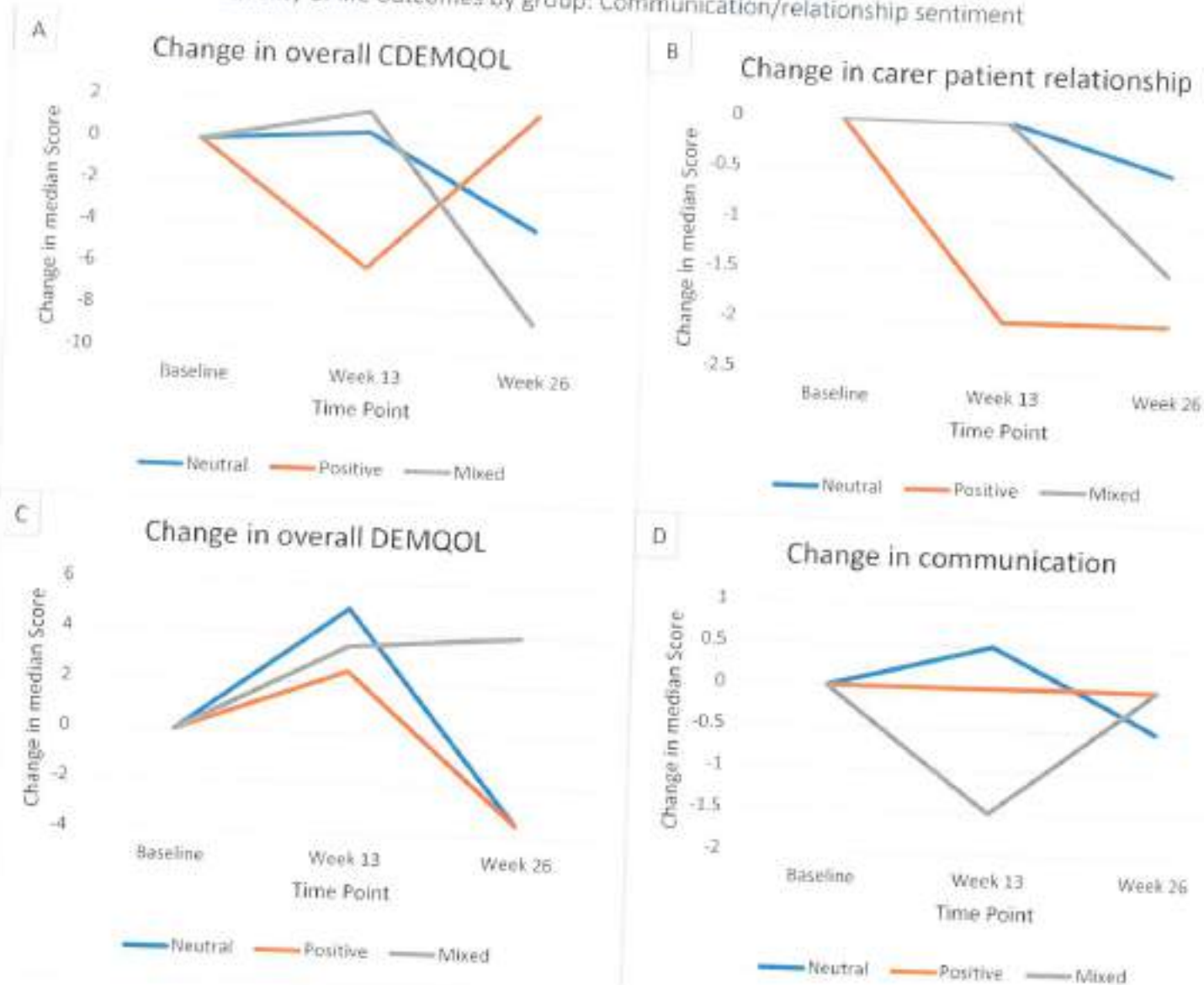


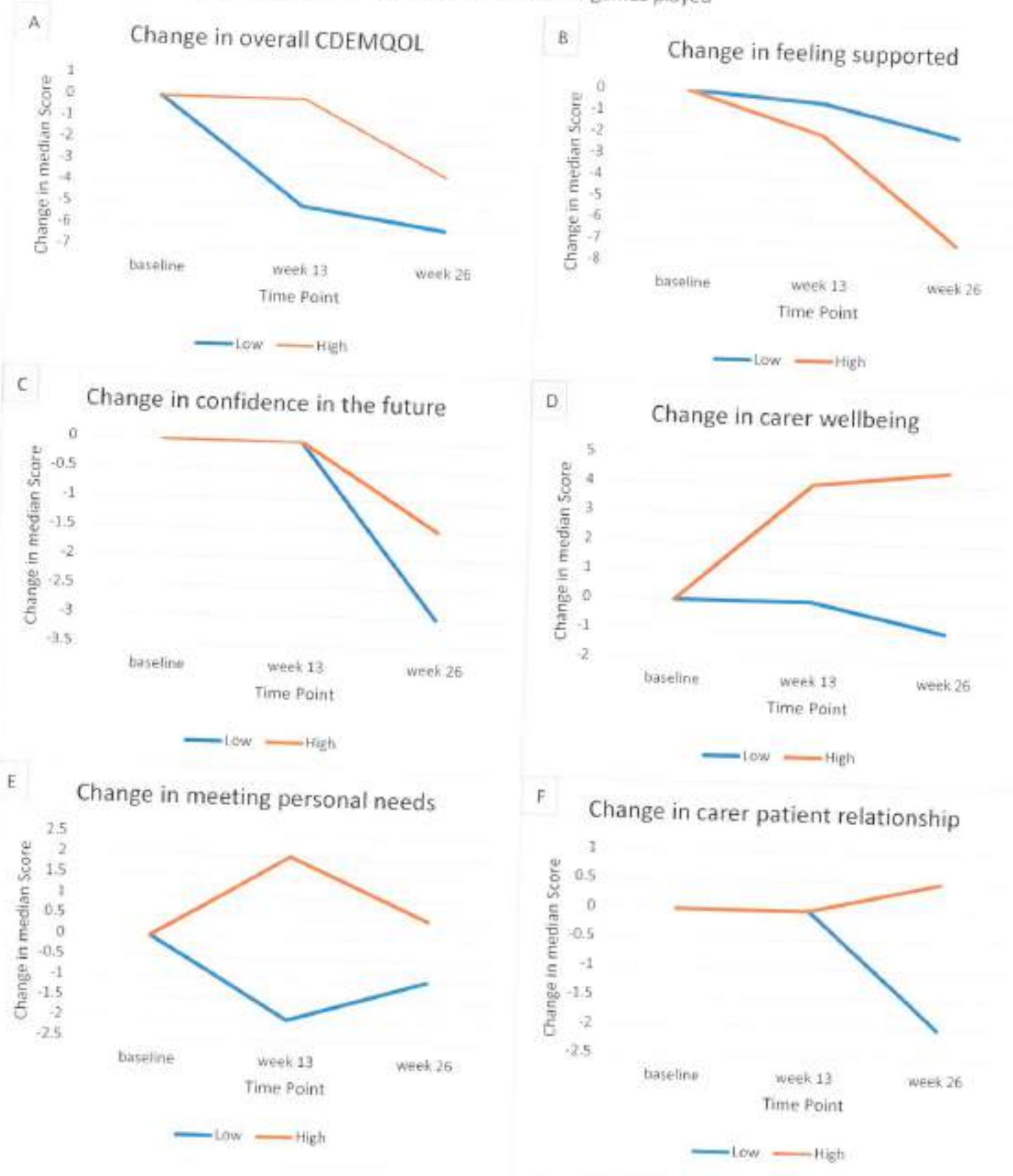
Figure 7. A – change in median overall CDEMQL grouped by communication/relationship sentiment from baseline to week 26. B – change in median ‘carer patient relationship’ grouped by communication/relationship sentiment from baseline to week 26. C – change in median overall DEMQOL grouped by communication/relationship sentiment from baseline to week 26. D – change in median ‘communication’ grouped by communication/relationship sentiment from baseline to week 26.

When grouped by communication/relationship sentiment (C/R sentiment) participants with a positive C/R sentiment exhibit an increase in median overall CDEMQL scores (1.5) from baseline to week 26, and a decrease in both ‘carer patient relationship’ scores (-2) and overall DEMQOL scores (-3.5) overtime. Median ‘communication’ scores showed no change from baseline to week 16.

Those with a neutral C/R sentiment showed a decrease in median overall CDEMQL scores (-4), 'carer patient relationship' scores (-0.5), overall DEMQL scores (-3.5), and 'communication' scores (-0.5) from baseline to week 26.

Participants with a mixed C/R sentiment exhibited a decrease in median overall CDEMQL scores (-8.5), and 'carer patient relationship' scores (-1.5) from baseline to week 26. An increase is seen in median overall DEMQL scores (4), and median 'communication' scores remain stable from baseline to week 26.

2.8.7 Quality of life outcomes by group: Number of games played



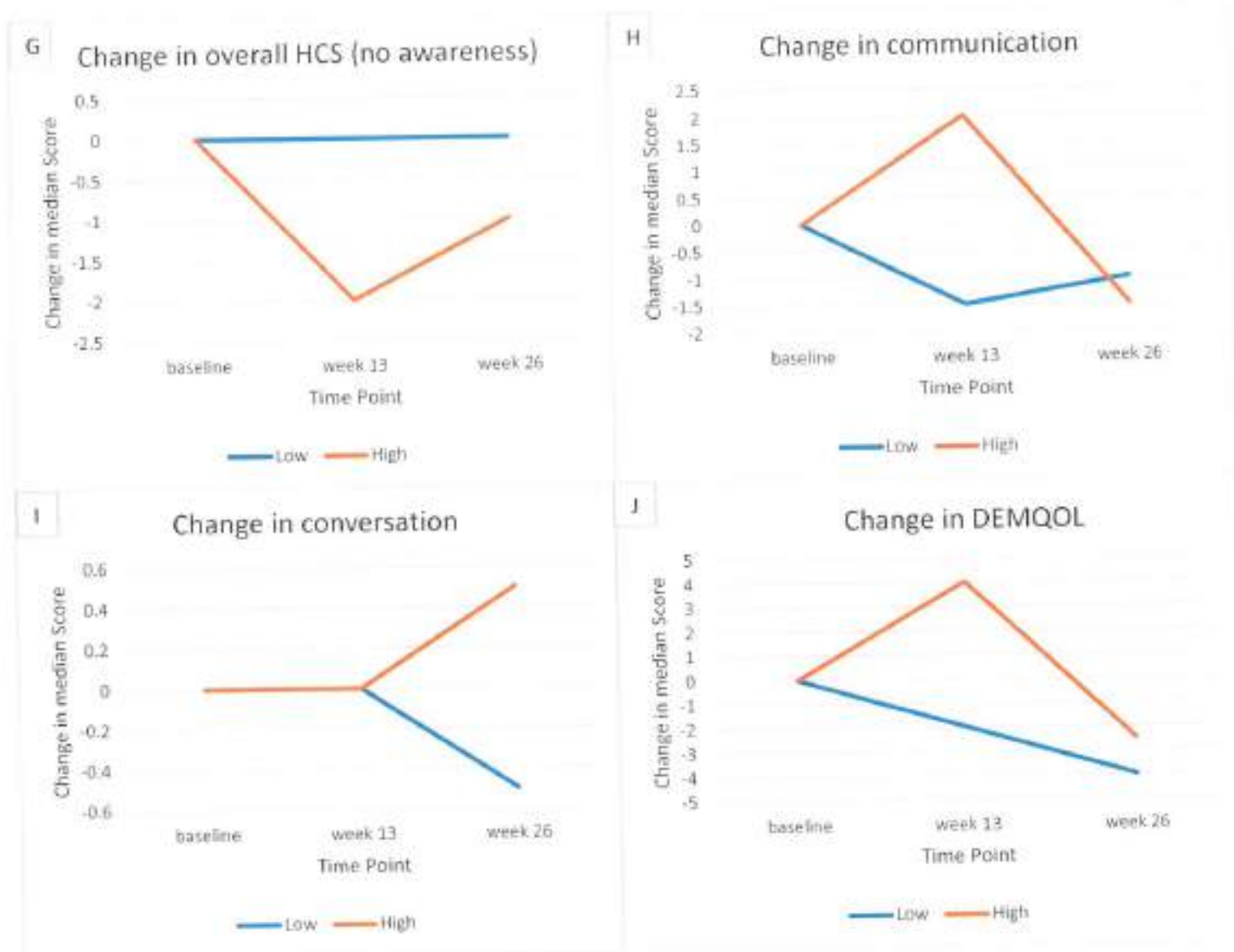


Figure 8. A – change in median overall CDEMQOL grouped by average number of games played from baseline to week 26. B – change in median ‘feeling supported’ grouped by average number of games played from baseline to week 26. C – change in median ‘confidence in the future’ grouped by average number of games played from baseline to week 26. D – change in median ‘carer wellbeing’ grouped by average number of games played from baseline to week 26. E – change in median ‘meeting personal needs’ grouped by average number of games played from baseline to week 26. F – change in median ‘carer patient relationship’ grouped by average number of games played from baseline to week 26. G – change in median overall HCS (no awareness) grouped by average number of games played from baseline to week 26. H – change in median ‘communication’ grouped by average number of games played from baseline to week 26. I – change in median ‘conversation’ grouped by average number of games played from baseline to week 26. J – change in median DEMQOL scores grouped by average number of games played from baseline to week 26.

When grouped by average number of games played from baseline to week 26 participants with a high average number of games played exhibit a decrease in median overall CDEMQL scores (-3.5), 'feeling supported' scores (-7), 'confidence in the future' scores (-1.5), overall HCS (no awareness) scores (-1), and 'communication' scores (-1.5) from baseline to week 26. Those who have a high average number of games played show an increase in median 'carer wellbeing' scores (4.5), 'meeting personal needs' scores (0.5), 'carer patient relationship' scores (0.5), and 'conversation' scores (0.5) from baseline to week 26.

Participants with low average number of games showed a decrease from baseline to week 26 in median overall CDEMQL scores (-6), 'feeling supported' scores (-2), 'confidence in the future' scores (-3), 'carer wellbeing' scores (-1), 'meeting personal needs' scores (-1), 'carer patient relationship' scores (-2), 'communication' scores (-1), and 'conversation' scores (-0.5). Median overall HCS (no awareness) exhibited no change in scores from baseline to week 26.

2.9 Questionnaire Data

At week 26 a supplementary questionnaire was administered before the semi-structured interview. The questions were developed using themes from the week 13 semi-structured interview to help draw out more information. Both sections of the questionnaire were completed by the carer, the first relates to the carers thoughts and feelings, seen in Figure 9, the second relates to how the carer feels the PWD is feeling, seen in Figure 10.

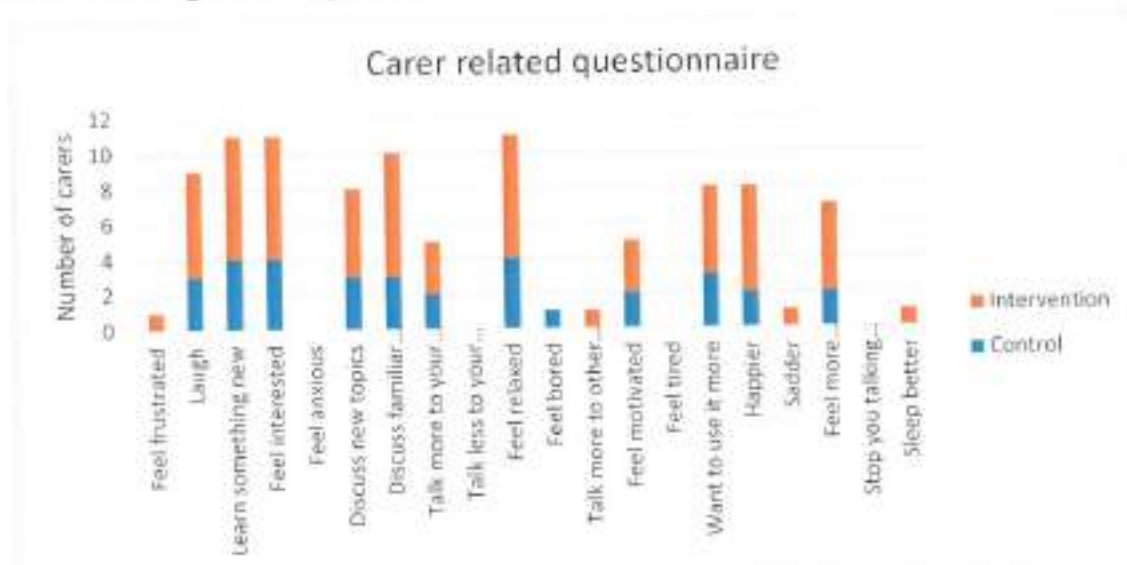


Figure 9. Carer related questionnaire, completed by the carer. The graph represents the number of participants who agree with the given statement, each statement is grouped into control and intervention.

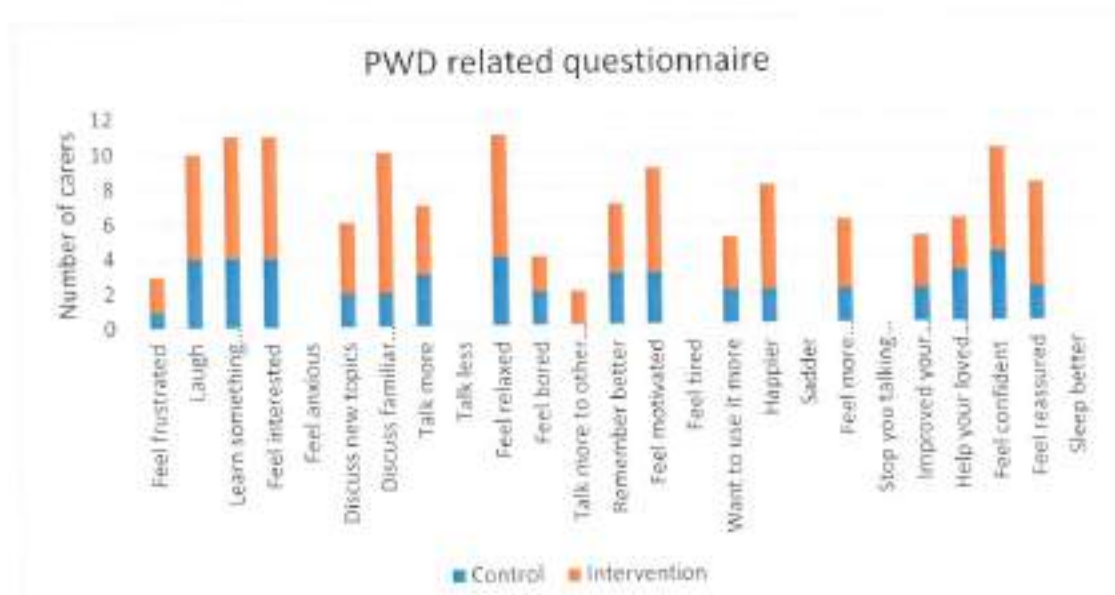


Figure 10. PWD related questionnaire, completed on behalf of the PWD by the carer. The graph represents the number of participants who agree with the given statement, each statement is split into control and intervention.

2.10 Themes from qualitative data

The following section covers the themes which emerged from the interview data. All relevant themes and associated comments are included so that the richness of the data can be appreciated. The headings for each sub-section show the theme which the comments appear to describe.

2.10.1 Accessibility

- 2 carers (17%, both are control) believe that the iPad and the app was very accessible *'seeing her navigating and doing it all. It's just been perfect'*. A carer mentions that even though the PWD is unfamiliar with technology they were still able to navigate the app *'with not being familiar with the iPad he just seemed to be quite happy to work his way through it'*. One carer even mentions that due to the ease of use of the app she was able to let the PWD get on with it, which then may have given her time to do her own thing, *'she was kind of up and running quite quickly, which is why I felt confident that I could leave her to get on with it'*.
- 4 carers mentioned something negative about the app's accessibility and usability. One mentioned, *'if the carer hasn't got time, the person who it's meant for isn't going to pick it up and do it'*, they had to be there to help them use it so it was using up their time – it could not be used as a distraction technique. One carer found the speed of the app quite slow for where the PWD was in their dementia journey, *'the ability to set the speed at which the questions come up because we found that quite slow'*. 2 carers found that the PWD was not already comfortable with technology, so the iPad became a barrier *'she'll often just struggle with the basics of picking... [R: the tablet up?] yeah, yeah', 'he'd end up pressing buttons and things would go off in a direction he wasn't expecting, and then he'd give up'*.

2.10.2 Communication

- 50% of carers mention that it has positively affected their communication in some way.

2.10.3 Creating connection

- Carers mention that it has helped them bond or create some kind of connection. *'it's felt like it's something that's just her and I have done as well'*. One intervention carer mentions that it has helped the PWD bond with their grandchildren, *'That's something they [grandchildren] could do with him and not feel frustrated because he didn't understand'*. It may be that the simple nature of the app on a technology the younger generation is familiar with has helped bridge the gap between the two generations.
- One carer (control) mentions how they enjoyed the physical closeness the app created between them and the PWD, *'it's that closeness that I've really enjoyed [physical closeness]', 'I think that it brought us closer together, and at times she will go, she will go to give me a hug'*.

2.10.4 Conversation starter

- 3 carers (25%) mention that it has helped them start conversations with one another and prompt interactions, *'it helped us to discuss topics with questions that came up, we could maybe use it to prompt a memory'*. 2 carers (17%) mention that the app encouraged them to talk about new topics, *'I'd never have discussed a car with anybody'*, *'I don't think I even knew he has a dog when he was young'*.
- *'I think it made you talk; it does make you talk together more'*.
- One carer mentions that it has even helped give the PWD the confidence to start conversations where they normally wouldn't have *'P will talk about it, so she'll bring it up in a conversation where... she doesn't always start a conversation'*, *'it would quite often prompt a conversation, and sometimes they may not happen at all'*
- *'it's stimulated a bit of conversation, yes. Yes, so from that point of view, it was quite good.'*

2.10.5 Memories / reminiscence?

- 42% of carers directly mention the memories the app brought up and the conversations created from those memories. *'definitely did create some conversation because we talked about memories'*, *'it was bringing back memories from a long time ago'*.
- *'it's brought a lot of things back to us that were, we wouldn't have more or less talked about unless we brought old photographs out'* – intervention, the act of looking through photos to make the personalised games brought them joy and made them reminisce
- *'especially in the music ones. They were bringing back the memories of times gone by'*

2.10.6 Quality time together

- 4 different carers (33%) mention that they and/or the PWD enjoyed the quality time it created for them to spend together. *'it gives me and PWD something to do together'*, *'it was obviously an opportunity to do something together'*, *'he certainly enjoyed the grandchildren doing it with him'*, *'C: I think it's quite a good thing, actually. Sit down with him and do stuff like that'*.

2.10.7 Confidence

- 5 carers (42%) mention that the app has positively affected the PWD confidence in some way. *'he just felt more confident and happier'*, *'it was just so lovely seeing her being so proud of getting it right'*, *'she's quite confident. It's been quite shocking'*, *'I think this made him think 'oh yes, actually, I can do it.'*
- Two carers mention the confidence built in terms of using new technology *'it is the confidence of navigating. You know, that's just been incredible, because it's not something I have really seen*

before', 'the feeling confidence is because he likes being able to prove he can master something like that. I think that was the iPad use, rather than the app itself or the content of the app'.

2.10.8 Carer Lead

- 7 carers found that they had to prompt or lead the activity, instead of the PWD naturally picking up the app. This may add an element of stress to using the app for the carer as it may be adding to carer burden. *'she doesn't pick it up when she isn't prompted', 'PWD won't pick it up and play it herself. It's me, then having to remember', 'it's only because I ask him to do it, that he does it', 'he's not that bothered, I got the feeling perhaps he was really doing it because I'd asked him to do it', 'but I would have to prompt him to have a go, and I would usually do it with him.'*

2.10.9 Engagement

- 3 carers (all intervention) mention that using the app has been helpful to keep the PWD busy and mentally active. *'it's to just sort of maintain and keep going with her brain activity - if we're being blunt', 'it's stopped him from just sitting and watching the TV', 'first few weeks he would do it every day... that was really good because it was brain stimulation and he enjoyed it'.*
- One carer mentions that it was good to get the PWD doing something different, *'it's good from the point of view of making him do something different'.*
- 8 carers (67%) mention the PWD actively enjoying playing on the app. *'...when I kind of stepped away, and then it was, yes, she was enjoying it', 'she's just so in the moment of it, not running, not worrying about something else', 'you're being asked questions and you get the right answer, and that's a really nice feeling, isn't it?', 'I sort of feel a bit guilty that we haven't used it more often, because we both quite enjoyed it', 'He enjoys playing it, and he's happy when he gets it right'.*
- 8 carers (67%) make negative comments towards the engagement of the app.
 - o An overarching theme is the lack of categories and variety, especially in the control app (all control carers mentioned this). *'And we do a couple, and then you get a bit bored and that was it. I'm afraid!', 'if it was more stimulating, I think I would have gone to good', 'if there were fresh games, I'd definitely think that was really worthwhile', 'I think boredom set in a little bit, and, uh, he found it repetitive', 'I just don't think there was enough there, to keep it, to use it enough', 'if there was more content, there would be more conversation, and he would do it more often'.*
 - o Another theme was the difficulty of the games. Many participants thought the games were too easy. *'he found it fairly simple... It didn't really stretch his brain', 'He said a number of times they are too easy', 'R: she made the comment, does it think I am stupid?', 'I know it all, I am bored'.*

2.10.10 Carer distress

- 2 carers (both intervention) found using the app either frustrating or upsetting. *'I think it's nice to see P when he does get pleased himself doing it because it's almost like it's the old P... [carer becomes tearful]. 'every time he gives the wrong name, and he knows it... that makes me frustrated as I know that he knows'*.

2.10.11 PWD frustration / anxiety

- 4 carers mention feelings of frustration or anxiety for the PWD induced by using the app. One carer mentions frustration caused when getting answers wrong *'she'll just switch off thinking 'oh I've made a mess of that'. And switch it off...'*. Another mentions anxiousness when getting the answers incorrect *'she doesn't like it if she can't, she doesn't know. So that's when the anxiousness comes in and then she'll maybe quickly lose interest'*. One carer mentions that the tech became a barrier for them, and he made the PWD frustrated *'R: you've put that it made him feel frustrated C: well, that's the tech'*. Another carer mentions that the repetitive nature of the control app caused some frustration *'I think that's where the frustration came because it was the same ones... the same ones over and over'*.

2.10.12 Personalisation

- 2 carers had positive remarks to make about the personalisation process, *'of building? Yeah, because it brought other memories back', 'and the end article was great'*.
- 7 carers (58%) mentioned something negative to do with the process of personalisation and building games. *'the lack of access to the Internet was quite... because I couldn't find everything I wanted to find', 'R: and what about the search function? C: Oh, we don't really bother [laughs], 'it's like having homework to do at the end of the day', 'I just get my phone out and show him the pictures... So, they will generate exactly the same as this. This [the app] doesn't add anything to that'*.
- 4 of the 7 carers mentioned that they felt that building games took too long, and it ate into their time which is a valuable resource for informal carers. *'I just haven't had the time... I am just so busy all the time', 'well not really, it's just a fuff', 'it's just yeah, finding the time to sit down and do that is a bit of a problem... there's usually other things to do while I am here'*

2.10.13 Learning

- 3 carers mention they have learnt something by using the app
 - o *'PWD: I have learnt something'*
 - o *'she's getting more correct than previously'*
 - o *'I don't think I even knew he has a dog when he was young'*

3 Discussion

3.1 Impacts on Quality of Life

The study aimed to investigate the impacts of the app on QoL for both carers and PWD. The results showed that the intervention group did not exhibit a reduced decline in carer QoL at week 26 as was seen at week 13. Conversely, control participants demonstrated an increase in carer QoL, which was unexpected. When examining the dementia severity of the study sample, it was found that as dementia severity increases, carer QoL tends to decline. Therefore, there may be an unknown factor present in the control group that is causing carer QoL to increase over time. Further research is needed to explore this possibility and identify any potential factors that may be contributing to the observed trends in carer QoL.

It was observed that individuals who demonstrated high levels of adherence to the app at week 13 tended to exhibit a decreased decline in carer QoL. Conversely, those with low levels of adherence tended to experience a greater decrease in carer QoL. However, the trend was reversed at week 26, where high adherence was associated with a decline in carer QoL, and low adherence was associated with a reduced decline. This discrepancy might be explained by the fact that carers initially perceived the app as beneficial to their QoL, but over time, 75% of carers found it tedious or time-consuming, which may have led to a decline in its effectiveness. One carer using the intervention app said in their semi-structured interview, *'I think boredom set in a little bit... he found it repetitive'*, another participant with the control app references boredom in their interview *'we do a couple, and then you get a bit bored and that was it'*. The time-consuming nature of the personalisation process was mentioned by 50% of the carers using the intervention app, *'it's just a faff'*, *'it's just something that again it's taking up my time when I could be doing something else'*. It may be possible to extend the benefits of the app by improving its engagement and personalisation features. Specifically, improving the process of creating personalised games and making the app more engaging for longer periods of time by creating more games. Further research and development in this area could help to optimize the app's effectiveness and maximise its potential benefits for both carers and PWDs.

For individuals with high adherence to the app, carer 'meeting personal needs' scores increased, while 'feeling supported' scores decreased. Conversely, in individuals with low adherence, the opposite pattern was observed. This trend might be caused by carers who feel they have less external support relying more on the app for comfort and thus engaging with it more frequently. However, it is also possible that carers who are able to meet their personal needs are more able to encourage and support the PWD in using the app regularly. 58% of carers reported feeling the need to prompt the

PWD to use the app, which may add to their stress. It is worth noting that 75% of carers stated that they only used the app as part of the research study.

Despite the overall decline in carer QoL among those who used the app consistently, 66% of carers believed that the time spent using the app was worthwhile, with 2 of them finding it very worthwhile. Furthermore, 33% of carers reported that the app had a positive impact on the PWD's thinking abilities. On the other hand, PWD QoL tended to increase in individuals with high adherence to the app, while those with low adherence tended to experience a decline in QoL. This suggests that the benefits of the app may be more pronounced for the PWD than for the carer. Additionally, it was observed that individuals with high adherence to the app experienced a decrease in scores related to the carer-patient relationship, while those with low adherence exhibited an increase. This could indicate that the app may be causing some strain on carers' perceptions of their relationship with the PWD, despite its positive effects on the latter's QoL.

It was found that participants who consistently played a high number of games on the app at week 26 tended to have higher overall QoL scores for both the carer and the PWD compared to those who played a low number of games per week. This trend may be due to the fact that while using the app consistently may initially be burdensome for carers, the more time they spend playing on the app and the more games they play, the slower the decline in QoL for both the carer and the PWD. Further research is needed to confirm this hypothesis.

Those who played a high number of games on the app tended to exhibit a higher decrease in scores related to feeling supported and a lower decrease in scores related to confidence in the future. It is possible that carers who feel they have less external support may turn to the app for support and thus play more games, leading to an increase in their confidence in the future. This trend may be influenced by the severity of dementia in the PWD. The analysis revealed that participants who played a high number of games tended to have a milder diagnosis compared to those who played a low number of games per week (25% of those with a high number of games played had a moderate diagnosis, compared to 57% of those with a low number of games played). Studies have shown that individuals with mild dementia tend to feel less supported than those with moderate dementia (Zank & Leipold, 2001). This could explain why carers with milder cases of dementia may seek support through playing more games on the app. The data also showed that over time, scores related to carer wellbeing and the ability to meet personal needs tended to increase for those with a high number of games played, while they decreased for those with a low number of games played per week. Additionally, PWDs who played more games per week also played on their own more frequently (an average of 51% of the time) compared to those who played fewer games per week (an average of 22% of the time). This

could suggest that when the PWD plays more games on their own, using the app as a distraction, it provides the carer with temporary respite and the opportunity to tend to their own needs and wellbeing. Research has shown that in-home respite can benefit carers by providing them with time to catch up on routine tasks, attend to domestic responsibilities, and prioritize their own health (Vandepitte et al., 2016). The use of digital health solutions, such as the app in this study, may also be beneficial to carer and PWD QoL (Martinez-Alcalá et al., 2016). It is worth exploring further whether the app's ability to provide carers with small intermittent breaks can reduce the decline in carer QoL.

The analysis showed that among participants who felt that the app was generally a positive addition to their lives, carers exhibited an increase in overall QoL from baseline to week 26. This finding suggests that carers may perceive the app as positive due to an improvement in their own QoL. The subcategories of 'meeting personal needs', 'carer wellbeing', and 'carer-patient relationship' showed the highest increase in scores or remained stable over time. This trend may be due to the fact that carers view the app positively because their own wellbeing and the relationship with the PWD are improving. This is supported by the questionnaire data, which showed that 92% of carers felt the app made them more relaxed and 67% felt that it made them happier. It is important to consider the possibility of inverse causality, as it may be that carers with a higher QoL tend to view the app more positively. Further research is needed to explore these relationships.

The analysis revealed that carers who had an overall positive sentiment towards the app tended to exhibit a larger decrease in scores related to confidence in the future and feeling supported compared to those with a neutral sentiment towards the app. At week 13, confidence in the future scores remained stable among carers who had a positive sentiment, while they decreased among those with a neutral sentiment. One possible explanation for this trend is that as participants engaged with the app less in the latter half of the study, their confidence in the future and feeling of support declined. Another possibility is that carers who feel they have less external support and are more concerned about the future may find more comfort in the app and thus view it more positively, leading to a decrease in scores related to confidence in the future and feeling supported among those who had positive sentiments.

3.2 Impact on communication / relationship

Communication was a common theme that emerged in the semi-structured interviews, and 42% of carers believed that the app had helped them communicate more with their loved one, while 58% believed it had helped the PWD communicate more. In fact, none of the carers reported that the app had led to a decrease in communication. 67% of carers believed that the app had helped them discuss

new topics with their loved one. It is possible that the app is fostering new conversations that contribute to an increase in scores related to conversation for individuals with a high number of games played. One carer even reported that the app had helped them learn more about their loved one by prompting them to discuss childhood memories that they had not previously talked about. The carer is quoted saying the following in their interview *'definitely did create some conversation because we talked about memories', 'I don't think I even knew he had a dog when he was young'*.

The analysis showed that 75% of participants with a high number of games played at week 26 had a positive sentiment towards the app, while 75% also believed that the app had made their interactions with the PWD 'more enjoyable.' This trend was also reflected in the scores for the CDEMQL subcategory 'carer-patient relationship', where individuals with a high number of games played tended to exhibit a slight increase in their scores, while those with a low number of games played tended to decrease. This suggests that carers who enjoy the app may do so in part because of the interactions it creates between them and the PWD, leading them to use the app more frequently. One carer even discussed that not only are the interactions the app is creating enjoyable but so is the physical closeness the app creates whilst they are using the app together, *'having that physical closeness has been, it's been quite nice as well', 'so she'll bring it up in a conversation where... she doesn't always start a conversation'*. It is worth exploring further the role of enjoyment in the use of the app and its impact on the carer-patient relationship.

Analysis revealed that among participants with a mixed C/R sentiment, there was a decrease in CDEMQL scores and an increase in DEMQL scores over time, as well as a reduction in scores related to the carer-patient relationship. This trend may be due to the fact that while carers in this group may find using the app stressful, the PWD may be experiencing the benefits in terms of QoL. Participants with mixed C/R sentiments discussed the reasons for their stress in the semi-structured interviews, while also acknowledging the benefits of using the app for the PWD. According to a carers' interview, the use of the app has elicited feelings of sadness and frustration due to the revelation of cognitive decline in the PWD. *'yeah, that does make me sad... I think he would have known that one time and... that makes me frustrated as I know that he knows'*. However, they go on to mention the benefits for the PWD, *'he's getting attention. I think he likes that'*. The second carer who had mixed C/R sentiments discussed why they found using the app with the PWD somewhat distressing, *'I think it's nice to see him when he does get pleased himself doing it because it's almost like it's the old him...'*. However, they also go on to mention the benefits of playing on the app together, *'I think that's a positive thing to do.'* It is possible that the decline in the carer-patient relationship may be due to the strain that the app places on their relationship, while the PWD is benefiting from the interactions and conversations it fosters.

Among participants with a positive C/R sentiment, there was an increase in CDEMQOL scores, a decrease in DEMQOL scores, and the largest decrease in scores related to the carer-patient relationship. This trend may be due to the fact that carers in this group, who already have a good QoL but have a low carer-patient relationship and a PWD with a low QoL, perceive the app as a positive addition to their communication and relationship dynamic with the PWD.

The analysis revealed that among participants with a neutral C/R sentiment, there was a decrease in CDEMQOL, DEMQOL, carer-patient relationship, and communication scores. This pattern may be because carers who had a neutral C/R sentiment did not experience any changes in their QoL or their relationship with the PWD as a result of using the app. However, it is worth noting that individuals with a neutral C/R sentiment exhibited the least decline in scores related to the carer-patient relationship. This might be because there is some aspect of the app that is causing strain on the relationship but further research is needed to explore this possibility.

The analysis showed that over time, 'carer-patient relationship' scores tended to increase for participants with a positive C/R sentiment, while those with both neutral and mixed C/R sentiments tended to exhibit a decrease. It is possible that carers with a mixed C/R sentiment find using the app with the PWD to be stressful or upsetting, leading to a decline in carer QoL. However, the PWD may still enjoy playing the app, which helps their QoL remain relatively stable over time and improves their HCS 'communication' scores.

Participants who had a positive sentiment towards the app tended to exhibit a reduced decrease in overall HCS scores compared to those with a neutral sentiment. However, those with a neutral sentiment towards the app tended to show a relatively stable 'communication' score over time, while those with a positive sentiment showed a decrease. This could be due to the fact that participants with declining communication may view the app in a more positive light, as it creates enjoyable and positive interactions between the carer and PWD, even if it does not directly improve the PWD's communication overall. For example, a carer states *'We really enjoyed it. And it gave discussion',* another discusses how the app helps increase communication *'I think it made you talk, it does make you talk together more.'*

3.3 Unanticipated Effects

It is interesting to note that participants with a low number of games played tended to show a reduced decrease in 'communication' scores and overall HCS scores, which both remained stable over time, compared to those with a high number of games played. 8% of carers reported that the app made them feel frustrated and 25% believed that it made the PWD feel frustrated. This may suggest that

although the app may be generating new conversations, the minor frustration it causes may also be contributing to a decline in communication and overall HCS scores over time, particularly among individuals who play more games. Further research is needed to explore this possibility and determine the extent to which frustration may impact the effectiveness of the app in improving communication and overall QoL.

4 Study Limitations

The study was carried out with a small sample size 12 participants (4 control, 8 intervention) therefore any themes or patterns extracted from analysis may not be fully representative of the target population.

All interviews, quality of life, and communication assessments were performed by the same clinical research nurse (not including the clinical dementia rating assessment which was performed by a separate assistant psychologist). This may introduce bias in how questions are delivered and recorded. On the other hand, it created consistency in measurement and recording.

There was no dedicated time to gain a rapport with the participants before the baseline data collection was performed. Therefore, participants may have been less comfortable with the researchers at the baseline visit compared to the week 13 and 26 visits (Samsi & Manthorpe, 2020). Also, some assessments were carried out while participants were fatigued. It is not clear how these facts might have affected data collection.

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