COPD PocketMedic Quantitative Evaluation

This report is designed to give a brief understanding of the analysis and results found for the Chronic Obstructive Pulmonary Disease PocketMedic clinical trial. If there are any questions, I would be more than happy to answer them. The best way to contact me is via email on: lik2@aber.ac.uk

Methods

The final version of the study consisted of three separate groups:

1. PocketMedic alongside Pulmonary Rehabilitation (PR)
2. Solely PocketMedic
3. Solely PR

The original study only consisted of groups one and three (obviously they were numbered differently at the time), however, due to problems with recruiting due to a lack of PR staff needed to run the service, another group consisting of solely patients who received PocketMedic was added. Unfortunately, although approximately 200 invitiation letters were sent out to people with COPD in Ceredigion, Wales, only a total of seven actually consented.

In total, the study recruited 53 participants, with 28, 7, and 18 in each of the three groups above. Participants were asked to complete a questionnaire booklet before they received the intervention, and once again afterwards. The booklet consisted of multiple separate questionnaires measuring participants' disease severity, quality of life (QoL), self-management knowledge, and disease knowledge.

Being a health psychologist, questionnaires investigating participants' self-determined motivation to self-manage, basic psychological needs, and the thwarting of these needs, were also included. These were included because the PocketMedic films were designed with Self-Determination Theory underpinnings.

PR attendance (for groups 1 and 3) and digital film engagement (for groups 1 and 2) was also measured.

Statistical tests were used to test if the research group the participant was in had an affect on scores obtained from the questionnaire booklet between the baseline and follow-up tests. Early on, however, it became clear that PocketMedic engagement was low, and this could have been masking some of the possible differences that those who did engage experienced. Throughout the report, 'non-engagers' refers to participants who did not watch any PocketMedic films; whereas, 'engagers' refer to participants who watched one or more films. Analyses were re-run. Both are reported below.

Primary Outcome

To investigate the effectiveness of PocketMedic by comparing levels of self-management knowledge and motivation between the two groups of participants who were prescribed the short digital films, with those who solely received PR.

Secondary outcomes

1) To compare the three groups on disease severity, quality of life, perceived psychological need satisfaction, need thwarting, and disease knowledge pre- and post-intervention.

2) To compare participants' PR adherence between those prescribed PocketMedic alongside PR with participants receiving solely PR.
3) To investigate which baseline patient characteristics, if any, can predict PocketMedic engagement.

Findings

Before analysing the results to meet the primary and secondary outcomes, all baseline measures were analysed to see if there were any differences between the group before they even took part in the intervention. The only difference between the three groups was participants receiving solely PocketMedic had a statistically lower disease knowledge score compared with the other two groups (35.71 vs. 47.93 and 50.25 for PocketMedic + PR and solely PR, respectively). Table 1 shows the average PocketMedic engagement and PR attendance for the three groups.

	PocketMedic and PR (n = 28)	PocketMedic (n = 7)	PR (n = 18)
PocketMedic films watched	2.93 (4.06)	7.0 (4.12)	-
PocketMedic films watched, excluding non-engagers	n = 12, 6.83 (3.35)	n = 6, 8.17 (2.99)	-
PR attendance (sessions completed)	10.33 (4.76)	-	9 (4.40)

Table 1: table displaying means and SD, in parentheses, for PocketMedic engagement and PR attendance between the three research groups.

Primary outcome

The first analysis found that irrespective of the research group participants were in, they showed similar scores between baseline and follow-up measures. When only looking at the variable of time (e.g. forgetting about the different research groups and looking at scores between baseline and follow-up), participants increased between time points to a significant degree for both self-management knowledge ($F(1, 36) = 19.91$, $p < 0.001$) and motivation ($F(1, 36) = 7.29$, $p < 0.05$).

When removing non-engagers from the analysis, it was found that although the research group did not significantly affect participants' motivation to self-manage, their self-management knowledge was different between the three groups. Post-hoc pairwise t-tests found a statistically significant difference between participants who received PocketMedic and PR to those who solely received PR (72.34 ± 11.75 vs. 60.90 ± 11.75, $p < 0.05$). This shows that people who received PocketMedic and PR (and engaged with the films), had a bigger increase in their self-management knowledge compared to those who did not engage, or did not receive PocketMedic and PR.

Secondary outcome one

To compare the three groups on disease severity, quality of life, perceived psychological need satisfaction, need thwarting, and disease knowledge pre- and post-intervention.

Analyses found that the variable of research group had a statistically significant effect on the variable of disease-knowledge. Post-hoc tests, however, did not report this difference. This contradiction, where one tests reports a difference and another does not, is not hugely uncommon

in statistics; however, this does have the potential to be a result of a lack of statistical power (most likely due to low sample sizes).

The other variables did not show a significant difference between the three research groups. None of these findings changed when excluding non-engagers from the analysis.

Secondary outcome two

To compare participants' PR adherence between those prescribed PocketMedic alongside PR with participants receiving solely PR.

Although descriptive statistics showed that participants receiving PocketMedic and PR had a slightly higher attendance rate compared to those who solely received PR (mean = 10.33, SD = 4.76 and mean = 9.00, SD = 4.40, respectively), this difference was non-significant. When excluding non-engagers, the mean for research group one did increase slightly (mean = 11.27), however, this did not affect the overall result.

Secondary outcome three

To investigate which baseline patient characteristics, if any, can predict PocketMedic engagement.

For this analysis, those who did and did not engage with PocketMedic in research group one had all their baseline measures investigated to see if there were any differences between them. It was found that one section of the self-management knowledge questionnaire (UCOPD Section A) and self-management motivation were significantly lower in participants who did non-engage with PocketMedic. This result is not surprising, if an individual has low knowledge on how to manage their condition or low motivation to do this, they'll be less likely to watch educational films on that very subject. It is mildly disappointing, as this patient group would most likely represent the people who would most benefit from the PocketMedic intervention.

<u>Further discussion</u>

It is important to be aware that the second analysis excluding PocketMedic non-engagers was conducted with a low sample size, where a total of 29 participants were included across the research conditions. However, it was necessary to reanalyse the results with the exclusion of participants to fully and accurately answer the research question; despite the loss in statistical power by doing so. Concluding that PocketMedic had no effect on participants' self-management knowledge (as was reported by the first analysis) could have represented a Type II error. This shows the possibility that the intervention's effects may have been hidden by those who did not engage, and clearly represents the justification for the exclusion of participants who failed to watch a single film.

Consistently throughout the analyses the effect of time was a significant factor, when holding research group constant. Although post-hoc tests to examine this difference would have been inappropriate, a comparison of the means shows measures taken at follow-up represented more beneficial states than those taken during baseline. This provides even more evidence for the already well reported benefits of PR, but also provides preliminary evidence for PocketMedic, due to participants in experimental condition two only receiving the digital films.

Although most of the analyses aim to highlight significant differences between the three research groups, the comparison between participants receiving solely PR and those receiving solely PocketMedic do not follow this same aim. Due to the overwhelming evidence of PR, PocketMedic only needs to show that its not inferior to this standard of care – represented by a lack of statistical significance.

Not one single statistical test reported significant differences between those receiving solely PocketMedic and those receiving solely PR. However, to maximise the chances of finding a statistical difference in non-inferiority studies, published literature a large sample size. There was a total of 25 participants within these conditions; thus, analyses clearly do not meet the recommended statistical power level. Statistical tests solely within participants receiving only PocketMedic would likely be flawed due to a total sample size of seven. Examining average scores at both time points for participants receiving solely PocketMedic, shows more beneficial outcomes at follow-up for every measured variable. Average self-management knowledge scores increased by 11.97. Self-management motivation by 17.14. Disease knowledge (BCQK) by 32.54, where the entire range for that questionnaire is only 100! The meaningful clinical significance level for the disease-severity measure used (COPD Assessment Test) is a change of 5 points; scores for participants within the PocketMedic only group demonstrate an average beneficial change of 5.57. Although, due to sample size, it would be inappropriate to generalise these findings, the results give support for the effectiveness of the link-delivered digital films, and the need for larger future research to investigate their efficacy further.

Patient recruitment has been a large problem throughout this research study, and I have to accept the resulting impact this low sample size had on the above analyses. Several strategies we re implemented to try and rectify poor recruitment, such as the addition of another experimental arm; however, unfortunately this did little to alleviate problems. The most appropriate method, which consisted of telephone calls to potential participants, was refused by the Research Ethics Council. Despite these issues, the above analyses found several meaningful and important statistical differences and it would be grossly inappropriate to indicate the lack of a statistically significant finding was the result of an analysis being underpowered. However, it would likely be unwise to overstate the generalisability of the above results. Therefore, for all the conclusions generated from this study, the author must state the findings *support* these conclusions, rather than *prove* them. Nevertheless, the findings do show clear support for the effectiveness of PocketMedic, where future research should investigate this further; potentially without prescribing the films alongside PR.