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EVALUATION OF AN RCT WEB BASED INTERVENTION FOR ADHERENCE IN CYSTIC FIBROSIS

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Objectives: On-line adherence programmes for adults with cystic fibrosis have not yet been fully evaluated. The aim of this trial was to determine the impact on adherence of a web-based intervention for adults with cystic fibrosis (CF).

Method: Participants were recruited from the adult CF unit (Leeds, UK) with random assignment to receive a web based adherence intervention (recruiting to n=50) or usual care (n=50). The web based intervention comprised 6 interactive on-line modules; Nutrition, Pancreatic enzyme replacement therapy, Vitamins, Liver disease, Antibiotics, and Respiratory and incorporated interactive materials and patient video inserts. Age, gender, presence of cystic fibrosis related diabetes (CFRD), cystic fibrosis liver disease (CFLD), microbiological status was recorded. The following primary outcome measures adherence (pharmacy refill) adherence (self-report DMI-CF), were recorded at baseline and 1 year. Secondary outcome measures including weight (kg), height (m), BMI(kg/m²), Vitamin A (µmol/l), Vitamin D (ng/ml), Vitamin E (µmol/l, urea and electrolytes, FEV1 (%), FVC (%), % rate of FEV1 (%) decline in previous 6 months, intravenous antibiotic therapy (IV) days in previous year, quality of life (CFQR) and knowledge (questionnaire). Interim measures (anthropometric, respiratory function/decline and vitamin status,) were collected at 6 months Analysis was undertaken using descriptive statistics and ANCOVA.

Results: Interim data for the cohort of patients [n=29 patients (16 intervention 13 control)] who had completed 6 months of the study are presented. Participants [intervention v control] were similar at baseline for gender, presence of CFRD, liver disease and microbiological status [pseudomonas 68.7% v 61.5%]. Age [29.2 v 29.8 years, p=0.83], Vitamin A [1.35 v 1.58 µmol/l, p=0.26], Vitamin D [66.2 v 84.3ng/ml, p=0.05], Vitamin E [23.8 v 23.0 µmol/l, p=0.86], FEV1(%) [40.0 v 48.3, p=0.27], coefficient variation FEV1 [0.14 v 0.14, p=1.0], coefficient variation weight 0.04 v 0.03, p=0.27] and iv days in previous year [56 v 66 days, p=0.64] were also similar at baseline. Adherence by self-report (DMI-CF) [70.4 v 77.5%, p=0.24] and pharmacy refill [54.6 v 66.0%, p=0.53] were noted. Adjusting for baseline values, interim secondary outcome measures collected at 6 months were noted. Participants accessing the web based intervention showed significant improvement in BMI [(F1,26) =7.1, p=0.01], Vitamin A [F(1,19) =5.8, p=0.03], Vitamin D [F(1,18) =5.13, p=0.04], Vitamin E [F(1,19) =6.8, p=0.02] above controls. No differences were observed in rate of lung decline in previous 6 months [F(1,26)=0.05 p=0.83], FEV1 [F(1,26)=1.17, p=0.89], nor CoVFEV1 [(F1,26)=0.002, p=0.96].

Conclusion: Interim data suggests significant improvements in secondary outcomes using an interactive web-based platform to inform and engage patients in their care. At 6 months, vitamin status and nutritional status showed significant improvements compared to controls. Full evaluation at 1 year is now required to evaluate whether improvements are sustained and overall improvement in adherence is observed.

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