

Impact case study (REF3)

Institution: Sheffield Hallam University		
Unit of Assessment: UOA04 - Psychology, Psychiatry and Neuroscience		
Title of case study: Increasing Adherence to Medication in Adults with Cystic Fibrosis		
Period when the underpinning research was undertaken: 2010 - 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): Madelynne Arden	Role(s) (e.g. job title): Professor of Health Psychology	Period(s) employed by submitting HEI: 2000 - present
Period when the claimed impact occurred: September 2017 - December 2020		
Is this case study continued from a case study submitted in 2014? No		

1. Summary of the impact

Cystic Fibrosis is a life-limiting condition affecting 10,500 people in the UK. Patients are usually prescribed three nebuliser treatments each day, however only 36% of treatments are taken. Non-adhering patients are more likely to need hospital treatments, which disrupt their lives and result in higher costs. Arden's research informed the development and refinement of an intervention 'CFHealthHub'. This intervention is now being used in clinical practice at more than three-fifths of sites in the UK, with more than 1400 patients registered by 2020, and significant NHS funds committed to its roll-out. It is being used by patients to self-manage their treatments and has increased treatment adherence by up to 18%. It has changed the practice of health professionals and the delivery of services within the NHS, generating health gains (0.17 QALYs) and offering cost savings of £2.5m per year.

2. Underpinning research

Cystic Fibrosis (CF) affects 10,500 people (6000 adults) in the UK, with patients experiencing life-limiting conditions and typically dying at 31 years of age. Patients are usually prescribed three treatments a day, taken through a nebuliser, which delivers medications directly to their lungs as a fine mist. Good adherence is vital for treatment effectiveness. However objective measurement shows only 36% of prescribed nebuliser treatments are taken.

The development of an intervention to promote nebuliser adherence in adults with CF was undertaken as part of a NIHR funded programme grant (total grant £2.5 million). The project team included Arden, as lead for the behaviour change strand, Martin Wildman (Sheffield Teaching Hospitals; clinical lead), Alicia O'Cathain (University of Sheffield) and academics from universities including Sheffield, Manchester and Queen's University Belfast. Arden was instrumental in the development of the intervention in the following three areas.

Identifying Key Barriers to Adherence

Interviews with a cohort of CF patients led to the identification of key barriers to adherence, with important differences between high and low adherers [R1]. This was the first study to use participants' personal objective adherence data as a prompt within an interview, to assess specific barriers and facilitators to treatment-taking, rather than relying on subjective recall of adherence (which is likely to be inaccurate). The research determined that the barriers and facilitators were highly variable, indicating that a one-size-fits-all intervention would not be appropriate. It was also

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found that there were key differences between higher and lower adherers, including that higher adherers had routines and habits for treatment-taking. Further analysis of the same interviews explored how participants used 'forgetting' in their explanations of non-adherence. Low adherers utilised 'forgetting' to present a socially acceptable reason for non-adherence, to help to normalise their behaviour, given that they knew they should adhere [R2]. This emphasised the importance of contextualising explanations with objectively-measured behavioural data and the importance of avoiding judgement in discussions about non-adherence.

Co-producing the Intervention with Patients and Clinicians using a Systematic Approach

The prototype CFHealthHub intervention was developed and launched in 2016 and comprised two parts: i) a web platform and smartphone app providing information and behaviour change tools that can be accessed by patients and health professionals, and ii) an intervention manual and training programme for health professionals to work alongside patients; this uses the web platform content and behaviour change tools to support patient adherence. The prototype was developed based on the barriers and facilitators established in R1, where Arden identified evidence-based behaviour change techniques to address each specific barrier. One of the techniques included was a type of coping plan called a volitional help sheet, shown to be effective in Arden's previous research [R6]. The intervention was co-produced and iteratively developed with patients and clinicians, with changes made in response to interview feedback and monitored use of CFHealthHub [R3].

Ensuring that the Intervention Worked in Practice

A research study ran in three UK sites, which randomised CF patients into 'intervention' and 'usual-care' groups. Measures taken pre-intervention and at five-month follow up found that the intervention was acceptable to patients and that those in the 'intervention' group showed a 10% increase in adherence [R4]. A process evaluation identified 14 key changes to the intervention procedures that were needed to maximise the chance of intervention success [R5].

3. References to the research

- R1.** Arden, M. A., Drabble, S., O'Cathain, A., Hutchings, M., & Wildman, M. (2019). Adherence to Medication in Adults with Cystic Fibrosis: An Investigation using Objective Adherence Data and the Theoretical Domains Framework. *British Journal of Health Psychology*, 24(2), 357-80. <https://doi.org/10.1111/bjhp.12357>
- R2.** Drabble, S. J., O'Cathain, A., Arden, M. A., Hutchings, M., Beever, D., & Wildman, M. (2019). When is Forgetting not Forgetting? A Discursive Analysis of Differences in Forgetting Talk between Adults with Cystic Fibrosis with Different Levels of Adherence to Nebulizer Treatments. *Qualitative Health Research*, 29(14), 2119-31. <https://doi.org/10.1177/1049732319856580>
- R3.** Arden, M.A., Hutchings, M., Whelan, P., Drabble, S.J., Beever, D., Bradley, J., Hind, D., Ainsworth, J., Maguire, C., Cantrill, H., O'Cathain, A., & Wildman, M. (2021; REF2 includes Covid delay statement). Development of an Intervention to Increase Adherence to Nebuliser Treatment in Adults with Cystic Fibrosis: CFHealthHub. *Pilot and Feasibility Studies*, 7(1). <https://doi.org/10.1186/s40814-020-00739-2>
- R4.** Hind, D., Drabble, S. J., Arden, M. A., Mandefield, L., Waterhouse, S., Maguire, C., ... & Keating, S. (2019). Supporting Medication Adherence for Adults with Cystic Fibrosis: A Randomised Feasibility Study. *BMC Pulmonary Medicine*, 19(1), 77. <https://doi.org/10.1186/s12890-019-0834-6>

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- R5.** Hind, D., Drabble, S. J., **Arden, M. A.**, Mandefield, L., Waterhouse, S., Maguire, C., ... & Keating, S. (2020). Feasibility Study for Supporting Medication Adherence for Adults with Cystic Fibrosis: Mixed-Methods Process Evaluation. *BMJ Open*, 10(10), e039089. <https://doi.org/10.1136/bmjopen-2020-039089>
- R6.** Armitage, C. J., & **Arden, M. A.** (2010). A Volitional Help Sheet to Increase Physical Activity in People with Low Socioeconomic Status: A Randomised Exploratory Trial. *Psychology and Health*, 25(10), 1129-45. <https://doi.org/10.1080/08870440903121638>

All articles were rigorously peer-reviewed prior to publication in leading journals in the field.

4. Details of the impact

The CFHealthHub intervention has had an impact on patients, service delivers and practitioners - delivering health, financial and skills benefits.

Benefits to Patients with Cystic Fibrosis

Research data showed that the intervention is successful in supporting patients to increase and importantly to maintain increased adherence to medication over a 12-month period. On average patients who received the intervention had 10% higher adherence than those receiving usual care. The difference was even more substantial in patients who started the trial with low (26-50%) or moderate (51-75%) adherence and received the intervention. Their adherence was 18% and 15% greater respectively than with usual care [E1].

Patients who receive the intervention reported decreased concerns about medication, lower perceived effort of treatment and increased habit strength. They also report lower perceived treatment burden, which is a top research priority in CF according to a recent priority setting exercise by the James Lind Alliance. Therefore, while patients are taking more of their treatment because of the intervention, this is not negatively impacting on their perceived treatment burden [E1].

The intervention also enhanced the patient experience. Interviews with patients indicated that they found CFHealthHub helpful in supporting their adherence: "*It's helped me find a pattern, which I didn't have before*" and "[it's] *drastically improved my using of treatments, my overall health and my understanding of CF*". Patients also appreciated the support they received from health professionals who delivered the intervention: "*It was good to have that one-on-one aspect and it kind of gave me the confidence to then continue without as many meetings*" [E2].

Increased patient involvement in shaping the intervention has resulted in a usable system that patients are invested in engaging with to improve their adherence [E2]. Patients chose to use the CFHealthHub system during the research [E1] and subsequently when it became available in clinical practice. Between August 2019 and December 2020, patients logged into CFHealthHub 28,135 times in total [E3].

Benefits to the Delivery of Cystic Fibrosis Services

CFHealthHub provides a tool that can easily be integrated into care pathways to inform medical decision-making and to increase adherence in CF patients. NHS England offered NHS Trusts across England £8 million of investment for the intervention to be rolled-out within care pathways for adults with CF as part of its 2019/20 Prescribed Specialised Services Commissioning for Quality and Innovation (CQUIN) scheme [E4]. This funding supported the adoption of CFHealthHub in 16 CF centres in England (Barts, Birmingham, Blackpool, Bristol, Exeter, Frimley, Leicester, Newcastle, Norfolk/Norwich, Nottingham, Oxford, Plymouth, Sheffield, Southampton, Stoke, Truro and York). CFHealthHub has also been adopted in Belfast, Cardiff and Edinburgh

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under separate arrangements with the devolved nations. CFHealthHub is therefore currently used in 19 out of 26 centres in the UK, with 1416 patients registered by the end of 2020, representing around 24% of adults with CF [E5].

An NIHR economic analysis of the intervention calculated that it generated health gains of 0.17 additional QALYs and cost savings of £1,790 per patient per year, compared with usual care. The savings are from both reduce medicine wastage and lower the risk of exacerbations that lead to hospitalisation. This is therefore offering estimated savings to CF service delivers of £2.5 million annually (£1,790 average saving x 1416 patients already registered) [E1].

The coronavirus pandemic posed a particular problem for the care of people with CF, who were classified as clinically extremely vulnerable and were asked to shield during the early part of the pandemic. CFHealthHub was recommended by NICE as an innovation that allowed remote delivery of care, with virtual clinics supporting people and providing them with behaviour change tools to self-manage their condition while they were shielding:

“CFHealthHub enables remote monitoring and virtual clinics for people with CF. This is critical for CF monitoring during the COVID-19 pandemic” [E6].

The intervention has also been adapted for use in paediatric settings in the UK, with the first feasibility study having begun in Southampton [E7].

There has been international interest in CFHealthHub, with CF centres in the USA and France having expressed an interest in adopting it [E7].

Benefits to Health Practitioners

Health professionals delivering adherence support to patients, including physiotherapists, pharmacists, nurses and psychologists, have benefitted from CFHealthHub. Practitioners have increased their skills, knowledge and capability for supporting patient adherence using CFHealthHub. Arden has delivered training in behaviour change and the use of CFHealthHub behaviour change strategies and tools to over 100 health professionals working in CF [E8].

Health professionals found the CFHealthHub enhanced their decision making and enabled a more patient-led approach within their practice. A survey of 85 healthcare professional conducted in November/December 2020 found that 95.3% agreed that CFHealthHub supported an open honest conversation that improved the patient-practitioner relationship, while 90.6% agreed that CFHealthHub provided tools to empower patients to self-care. [E9]. Interviews with health professionals confirmed that it significantly changed and improved their practice. One reported that:

“It changes your whole practice. I think you more ask open ended questions, rather than making assumptions. I think you learn different ways... and making that acceptable, and then something that you do together, is different than you sitting in a clinic and saying ‘well why aren’t you doing the nebuliser, it takes five minutes’”. Another acknowledged that: “It has definitely changed my practice in terms of the way that I approach things, it...[has become] more patient led now, rather than me firing questions and getting the answer that they think I want back.” [E9].

Experts who reviewed CFHealthHub as part of the NICE briefing stated that *“The innovative aspect of CFHealthHub is the included behaviour change tools”*, and that *“CFHealthHub had improved clinical consultations by enabling...honest discussion about the data...how the patient may be struggling with the burden of treatment...and how the CF team can support them.” [E6].*

Health professionals use CFHealthHub as a regular part of their practice. Currently 412 clinicians across 19 UK sites are registered to use CFHealthHub. Between August 2019 and December

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2020 there were an average of 1,517 clinician log-ins per month, during which healthcare professionals looked at patients' adherence data pages 34,541 times in total [E3].

5. Sources to corroborate the impact

- E1.** Development and Evaluation of an Intervention to Support Adherence to Treatment in Adults with Cystic Fibrosis: The ACtiF Research Programme (NIHR Report; to be published in 2021, in press version available on request)
- E2.** Patient experience interview data extracts
- E3.** Patient and Health professionals click analytic data from the data observatory sites up until 31/12/20
- E4.** CQUIN funding document from NHS England
- E5.** CFHealthHub data observatory recruitment figures Dec 2020
- E6.** NICE briefing on CFHealthHub.
<https://www.nice.org.uk/advice/mib219/resources/cfhealthhub-for-managing-cystic-fibrosis-during-the-covid19-pandemic-pdf-2285965459946437>
- E7.** Documents about international update and paediatric study protocol
- E8.** Compiled documents relating to training
- E9.** Health professional users of CFHealthHub interview data extracts and survey results