Manuscript Details

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Title	Using air-quality feedback to encourage disadvantaged parents to create a smoke-free home: results from a randomised controlled trial
Article type	Research Paper

Abstract

Objective: To determine if low-cost air-guality monitors providing personalised feedback of household second-hand smoke (SHS) concentrations plus standard health service advice on SHS were more effective than standard advice in helping parents protect their child from SHS. Design: A randomised controlled trial of a personalised intervention delivered to disadvantaged mothers who were exposed to SHS at home. Changes in household concentrations of fine Particulate Matter (PM2.5) were the primary outcome. Methods: Air-guality monitors measured household PM2.5 concentrations over approximately 6 days at baseline and at one-month and six-months post-intervention. Data on smoking and smoking-rules were gathered. Participants were randomised to either Group A (standard health service advice on SHS) or Group B (standard advice plus personalised air-quality feedback). Group B participants received personalised air-guality feedback after the baseline measurement and at 1-month. Both groups received air-guality feedback at 6-months. Results: 120 mothers were recruited of whom 117 were randomised. Follow up was completed after 1-month in 102 and at 6-months in 78 participants. There was no statistically significant reduction in PM2.5 concentrations by either intervention type at 1-month or 6-months, nor significant differences between the two groups at 1-month (p=0.76) and 6-month follow-up (p=0.16). Conclusions: Neither standard advice nor standard advice plus personalised air-quality feedback were effective in reducing PM2.5 concentrations in deprived households where smoking occurred. Finding ways of identifying homes where air-guality feedback can be a useful tool to change household smoking behaviour is important to ensure resources are targeted successfully.

Keywords	Indoor air quality; Environmental Tobacco Smoke; Second-hand Smoke; Children; PM2.5; Education
Taxonomy	Exposure by Inhalation, Indoor Exposure Monitoring, Environmental Health Exposure
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Suggested reviewers	Emilia Zainal Abidin, Kamran Siddiqi, Esteve Fernandez

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Research Data Related to this Submission

There are no linked research data sets for this submission. The following reason is given: Data will be made available on request

Dear Editor

We have pleasure in re-submitting our manuscript 'Using air-quality feedback to encourage disadvantaged parents to create a smoke-free home: results from a randomised controlled trial' for consideration by Environmental International. We are delighted that the three reviewers provided such positive comments on our previous manuscript and have given us the opportunity to further strengthen our work. We include a word file explaining in detail the changes we have made in response to the reviewers' comments, together with a tracked changes version of the new manuscript and a clean (changes accepted) version.

We have carried out these changes as quickly as possible as we note that our funder (the Chief Scientist Office in Scotland) has a process of providing open access funding fees provided the paper is accepted within 18 months from the end of the project http://www.cso.scot.nhs.uk/outputs/cso-open-access-policy/. As the project ended on 31/01/17 this date is, for us, 31st July 2018. We fully understand that it may not be possible to reach a decision on our changes in this tight timescale but if there was any way of doing so then we would be very grateful.

We can again confirm that the work has not been previously published and is not under consideration by any other journal.

Best wishes

Sean

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Journal: Environment International

Response to reviewers' comments

We are extremely grateful to the reviewers for their time and effort in reviewing this manuscript and for recognising the novelty and importance of the work. The comments have been helpful in our revision of this work. We provide detailed responses to each point in the document below and have used tracked changes to the initial manuscript to assist with the re-review.

Reviewer #1

This manuscript presents the results of a RCT of a novel intervention to reduce SHS exposure in homes using air-quality monitors. The RCT shows an excellent design and execution. The authors show the results that indicate a lack of positive effect of the intervention, and discuss the reasons for such a lack of effect. In my opinion the clarity and transparency how the authors report the results is very important and hence I want to congratulate the authors. Moreover, they discuss in-depth the potential explanations for these results.

Response

Thank you for these positive comments which we really appreciate. We are delighted that you found the paper provides a clear and transparent write-up of this important study.

1.1 Introduction. The introduction is too long and in my view some paragraphs could be omitted or moved to the Discussion: 3rd paragraph, and first half of the 5th paragraph.

Response

We have shortened the length of the introduction as the reviewer advised. We have moved most of the 3rd paragraph to the section of the discussion comparing our results to previous studies and also moved the first sentence of paragraph 5 to the beginning of the discussion.

1.2. Methods: It is not clear in which exactly consist the intervention, since part of it is explained under the heading 1.1 and part of it under the heading 1.5. In my opinion, the clarity of the Methods section would be improved by assigning a new heading "1.2" labelled "Intervention" in which the intervention is explained (with part of the material currently in 1.1 and the former 1.5 heading). **Response**

We have re-written the methods sections as advised. There is now a clear section describing the intervention using some of the material from sections 1.1 and 1.5. We hope this brings greater clarity and also addresses reviewer point 1.3 below.

1.3. Moreover, please indicate in the text the moments when the feedback is provided, since it only appears in the figure. It has to be clearly stated that the intervention is the use of the air-quality monitors AND the feed-back provided, and in this sense, the frequency and timing of the feed-back is essential.

Response

We have now added this information to the new intervention section of the methods and further emphasised the timing of feedback in the 'PM2.5 measurement' section.

1.4. In fact, I believe that the lack of effect of the intervention could be attributed to the "low" intensity of intervention, this is, in the frequency of the feed-back. Discussion: As previously

mentioned, the authors should elaborate about the regime of the feed-back provided as the potential reason for the lack of effect (part of this idea is currently almost at the end of the Discussion). **Response**

This is an excellent point and we have now added some text to our discussion to highlight the fact that air quality feedback was provided on just a single occasion prior to the follow-up measurement. This is now combined with the discussion about Klepeis' study using immediate alarms when PM2.5 concentrations increase and our own study (TACKSHS) that will provide daily feedback to smokers about their household air quality.

Reviewer #2

Smoke-free homes is a matter of public concern and health and therefore, both researchers and health stakeholders would be interested in the current study. In the manuscript by Semple et al., the authors describe an intervention study on changes in tobacco smoke pollution in the home, as measured by air particulate matter (PM2.5) concentration. Overall this is a very interesting study, thoroughly conducted, executed and presented.

Response

We thank the reviewer for their encouraging words about the study and our presentation of the findings.

2.1 In the limitations section of the manuscript, the authors <u>do</u> state that $PM_{2.5}$ is produced by various sources and therefore its application as surrogate marker for SHS, should be implemented with caution. However, there is also a large seasonal variation of outdoors/indoors $PM_{2.5}$ concentration due to other than SHS sources, which should also be taken into consideration, particularly in a study like the one by Semple et al. which was conducted almost throughout one whole year. Information on the time (e.g. month) each step of the study was conducted as well as on the means of indoor heating of the two groups should be given.

Response

This is an interesting point and highlights one of the advantages of carrying out work in Scotland on measuring SHS. As we note, and as the reviewer recognises, PM2.5 is produced by other sources not least ambient air pollution. However, air quality even in urban areas of Scotland tends to be very good with low levels of ambient PM2.5 and there is very little seasonal variation. We have checked the government air quality data for the whole of 2015 (the year most of the fieldwork was carried out) at the urban outdoor monitoring site in Lanarkshire. The monthly daily averages of PM10 (typically PM2.5 is about two-thirds of PM10 values) range from 14 to 21 ug/m3 with no discernible seasonal pattern (see figure below). This, together with the fact that heating in Scottish households is almost universally by electric and closed system gas central heating systems with no PM emissions, suggest that most PM measured in these home settings comes from smoking activity. We have added some additional text to the discussion to reflect these points.

Statistics for South Lanarkshire Hamilton

Year:

2015 •

Parameter:

PM10 particulate matter (Hourly measured) **•**

Update Statistics

Monthly Statistics (monthly averages) for 2015

The monthly data below are average concentration data, followed by data capture rates (shown as a percentage of each month).

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
16	19	21	19	15	16	14	16	17	21	16	17
98%	99%	99%	100%	68%	100%	97%	98%	98%	80%	100%	86%

Annual Statistics for 2015

Annual Hourly Mean	17	µg/m ³ (TEOM FDMS)	Ratified	93% DC
Max Daily Mean	69	µg/m ³ (TEOM FDMS)	Ratified	93% DC
Max Hourly Mean	210	µg/m ³ (TEOM FDMS)	Ratified	93% DC

Data taken from http://www.scottishairquality.co.uk/latest/site-info?site_id=SL05&view=statistics

2.2. There is a confusion regarding the periods between baseline and follow up periods: are they 1 and six months or 3 and 15 weeks (fig 1)?

Response

The baseline measurement takes place between visit 1 and 2 with feedback provided usually about 1 week later. The follow-up periods were targeted at 1 month and 6 months later but the exact dates varied depending on availability of the participant. We have added some text to the methods ('intervention' section) to clarify this for the reader.

2.3. Table 2 shows medians and confidence intervals while the relevant text (lines 738-744) shows medians and IQR. This is also confusing, should be the same.

Response

We have made this change to the results section and now present just the medians and 95% confidence interval.

2.4. Figure 2 line 794:" Then" instead of "the" Response We have made this change.

2.5. Throughout the text: punctuation marks should follow the bracketed references (e.g. line 183 ...with a smoker[6-7]. instead ofwith a smoker.[6-7])

Response

We have made this change throughout the manuscript.

Reviewer #3

The article is highly novel, attempting to find ways to help population who are still being continually exposed to SHS despite the many advancement achieved in this field, especially in Scotland. The article combines behavioural-based science and hygiene methods and is highly relevant to public

health professionals, not to mention countries itself, as many countries within the UN group is attempting to achieve the end game of tobacco by 2025 in some countries and 2045 in other parts of the world. Although this manuscript does not really represent example of what is working, identifying the barriers to a successful intervention is also a gap in itself, which will help other researchers in the future. As the manuscript is already well-written, minimal comments are given. **Response**

We thank the reviewer for their encouraging comments and recognition of the fact that it is equally important to publish the studies of negative findings.

3.1. Introduction, page 7 - The meta-analysis indicated that these approaches generally had an impact on reducing household PM2.5 or air nicotine levels; though all studies reported evidence of continuing SHS 'contamination' post-intervention. – explanation on PM2.5 within this paragraph will help readers improve understanding.

Response

We have now defined PM2.5 within the paragraph as suggested to make this sentence easier for the reader to understand.

3.2 Methodology - NHS SHS advice information. Suggest adding some detail and maybe any report of the effectiveness (or non-effectiveness) of the information in helping parents. What are the advice specifically asked? This info may be relevant in encouraging NHS to improve information or tailor-made info based on the types of population being focused on.

Response

See response to point 1.2 where we now provide a clearer description of the intervention. The standard advice was 'Very Brief Advice' on second-hand smoke and children that was based around the UK National Centre for Smoking Cessation and Training and a local National Health Service Lanarkshire leaflet highlighting the health harms of SHS. We are not aware of any studies that have evaluated the effectiveness of this standard advice. The reviewer's point is therefore now incorporated in the final discussion where we note that those receiving the standard advice did not achieve any statistically significant improvement at follow-up suggesting that improvements and targeting of this advice may be required.

3.3 Suggest to add information with regards to the location of measurement and why living room was specifically chosen. How does the measurement represents the exposure to the children? What are the evidence?

Response

This is a great point and to address this we've now added text explaining that the living room was selected as (a) the room in the home where people spend most waking time in the home and (b) there is evidence from Spain showing a high correlation between nicotine concentrations measured in the living room and child's bedroom. We have also previously reported a small study showing associations between bedroom and living room PM levels in smoking homes http://journals.sagepub.com/doi/full/10.1177/1420326X14527301

3.4. SHS feedback, suggest some info on the WHO 25 μ g/m3 threshold in text to explain about its significance, in terms of health etc.

Response

We have added information in the methods section regarding feedback of information on household PM2.5 concentrations in relation to the WHO guidance value.

3.5. Minor comments, table 1, p=XXX, p can be deleted? Response We have made this change to table 1.

Using air-quality feedback to encourage disadvantaged parents to create a smokefree home: results from a randomised controlled trial

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Abstract word count: 243

Abstract

Objective: To determine if low-cost air-quality monitors providing personalised feedback of household second-hand smoke (SHS) concentrations plus standard health service advice on SHS were more effective than standard advice in helping parents protect their child from SHS.

Design: A randomised controlled trial of a personalised intervention delivered to disadvantaged mothers who were exposed to SHS at home. Changes in household concentrations of fine Particulate Matter ($PM_{2.5}$) were the primary outcome.

Methods: Air-quality monitors measured household PM_{2.5} concentrations over approximately 6 days at baseline and at one-month and six-months post-intervention. Data on smoking and smoking-rules were gathered. Participants were randomised to either Group A (standard health service advice on SHS) or Group B (standard advice plus personalised air-quality feedback). Group B participants received personalised air-quality feedback after the baseline measurement and at 1-month. Both groups received airquality feedback at 6-months.

Results: 120 mothers were recruited of whom 117 were randomised. Follow up was completed after 1-month in 102 and at 6-months in 78 participants. There was no statistically significant reduction in $PM_{2.5}$ concentrations by either intervention type at 1-month or 6-months, nor significant differences between the two groups at 1-month (p=0.76) and 6-month follow-up (p=0.16).

Conclusions: Neither standard advice nor standard advice plus personalised air-quality
 feedback were effective in reducing PM_{2.5} concentrations in deprived households where
 smoking occurred. Finding ways of identifying homes where air-quality feedback can be
 a useful tool to change household smoking behaviour is important to ensure resources are
 targeted successfully.

Keywords: Environmental Tobacco Smoke, Second-hand Smoke, Children, PM_{2.5}, Education, Intervention

1. Introduction

Second-hand tobacco smoke (SHS) is a common indoor air pollutant linked to a wide range of respiratory₅[1-2]_a cardiovascular [3] and early life ill-health effects₅[4]_a -with exposure more common in disadvantaged households-[5]_a Non-smokers who live with smokers can have high SHS exposures, particularly young children who spend much of their day at home with a smoker-[6-7]_a Globally it is estimated that 40% of children experience regular exposure to SHS with much of this exposure occurring in their own home-[8]_a. The global burden of this exposure is estimated to be over 600,000 deaths and almost 11 million disability-adjusted life-years per year. Children are particularly vulnerable to the effects of SHS exposure and suffer 28% of these deaths and 61% of this morbidity-[9]_a.

Enabling parents to create a smoke-free home is challenging but it is one of the key ways that children's exposure to SHS can be reduced globally. Scotland is at the forefront of protecting children from exposure to SHS with the Scottish Government's 'Take it Right Outside' campaign including a world first: a governmental target to reduce the proportion of children exposed to SHS at home by 50% (from 12% to 6%) by 2020-[10]. Increased adoption of smoke-free homes in low income populations has also been shown to increase cessation rates and prevent relapse-[11]. There is a need for good quality evidence on ways to increase the proportion of smoke-free homes in different settings. The most recent Cochrane review [12] of programmes to reduce children's exposure to SHS screened 57 relevant studies but identified that only 6 used objective measures of children's SHS exposure to evaluate intervention effectiveness. None of the included

studies used air-quality feedback. A recent systematic review and meta-analysis [13] identified seven interventions designed to encourage smoke-free homes that had used objective measures of household air quality as an outcome measure. The meta-analysis indicated that these approaches generally had an impact on reducing household-air concentrations of fine particulate matter ($PM_{2.5}$) or air-nicotine levelswithin the household; though all studies reported evidence of continuing SHS 'contamination' post-intervention.

Methods to measure SHS in indoor settings using airborne fine particulate matter ($PM_{2.5}$) as a marker of SHS concentrations have been used in tobacco control science over the past decade.[14-16]. Several studies have explored the concept of air-quality feedback to modify smoking behaviour in the home-[17-19]. The REFRESH study recruited 59 smoking mothers in Scotland and provided PM2.5 measurement data over a 24-hour period as the primary tool in a motivational interview aimed at empowering parents to make their home smoke-free.[17] That study found that mothers who received air-quality feedback reduced PM_{2.5} concentrations by approximately one-third although the study was too small to detect a difference with the control group. More recent work by Ratschen and colleagues [18] studied a similar approach with disadvantaged smoking parents in Nottingham. That study compared a complex intervention combining personalised air quality feedback, behavioural support and nicotine replacement therapy for temporary abstinence with usual care involving standard advice. The 24h PM_{2.5} concentration in intervention homes reduced exposure about one-third at the 12-week follow-up. Hughes et al [19] have reported an intervention involving an air-quality

instrument with warning lights and alarms to provide real-time feedback on particle concentrations in smokers' home. Their work showed an average reduction of approximately 19% in households receiving this feedback compared to just 6.5% reduction in control homes.

There are considerable challenges in rolling out this type air-quality feedback intervention at scale. <u>The REFRESH study</u> identified low recruitment rates (when potential participants were approached via GP letter); the high cost of available instruments and technical complexity; and the labour costs of delivering, setting up and collecting instruments from participants' home<u>s</u>-[20]. Recent work has identified lowcost air-quality monitoring devices that have the potential to address the practical problems of noise, cost and complexity of operation identified in previous studies-[21].

This study is the first to trial the use of air-quality feedback as an intervention to encourage smoke-free homes delivered in a real-world setting as part of health professionals' routine work with smoking clients. It was nested within the First Steps Programme (FSP) in Lanarkshire in Scotland [22], providing an opportunity to overcome many of the barriers identified in the REFRESH study [23] in terms of recruiting disadvantaged parents, embedding the intervention within an existing service and use of a simpler, low-cost device to deliver air quality feedback. The aim <u>of the study</u> was to determine if delivery of personalised air-quality feedback plus standard advice on the health effects of SHS was more effective than standard advice on its own in encouraging changes to household smoking as measured by objective assessment of PM_{2.5}

concentrations one-month later. <u>The study was nested within the First Steps Programme</u> (FSP) in Lanarkshire in Scotland [22], providing an opportunity to overcome many of the barriers identified in the REFRESH study [23] in terms of recruiting disadvantaged parents, embedding the intervention within an existing service and use of a simpler, lowcost device to deliver air quality feedback.

Methods

1.1. Study design

This was a randomised controlled trial which compared standard advice to achieve a smoke-free home against standard advice plus personalised air-quality feedback. Vulnerable mothers who smoked or lived with smokers and were engaged with the Lanarkshire FSP were eligible. <u>FSP is an early intervention programme provided by the National Health Service in Lanarkshire, Scotland, providing vulnerable first-time mums with intensive, free, one-to-one support during and after pregnancy to give their babies the best possible start in life. Support includes considering the child's exposure to SHS and where appropriate exploring options to reduce this. Over 30% of mothers involved in the programme are smokers with 48% of homes having one or more smoking adult resident.</u>

First Steps (FS) workers identified clients who were thought likely to have SHS exposure in the home either from self-report of household smoking or observations of the presence of SHS within the home. Participants were excluded from the study if they were: under 16; they were unable to give informed consent due to physical or mental incapacity; or there was no smoker resident within the household. FS workers identified clients who were thought likely to have SHS exposure in the home either from self-report of household smoking or observations of the presence of SHS within the home. These clients were invited to take part in the study, <u>I</u>information sheets were provided and written informed consent gained. PM_{2.5} measurements were made after randomisation, and one and six months afterwards. Participants were randomised to group A or B by a

member of the research team blind to the participants' details, using the ID number and randomisation function in Microsoft Excel. A short baseline questionnaire was completed to determine self-reported current smoking, household smoking rules and attitudes towards smoking. Group A participants received only standard NHS advice on the harmful effects of SHS after the baseline visit. Air-quality feedback was provided to this group only after the 6-month follow-up. Group B participants received standard NHS SHS advice plus personalised air-quality feedback at the baseline measurement. Project home visits were built into the existing FSP programme of weekly contacts with clients. Figure 1 shows the overall research design. Full engagement over the 6-month period involved nine visits where study materials were used.

Questionnaires assessed changes in smoking, household rules and quit attempts at the 1and 6-month follow-ups. All study participants received a £10 shopping voucher on completing the baseline and a further £20 on completion of the 6-month follow-up visit. The primary outcome was <u>change in the household $PM_{2.5}$ measurements-concentration</u> after one month. Ethical approval for the study was obtained from the NHS North of Scotland Research Ethics Committee (REC reference: 14/NS/0030; Protocol number: 2/012/14; IRAS project ID: 150095).

1.2. Lanarkshire FSP-Intervention

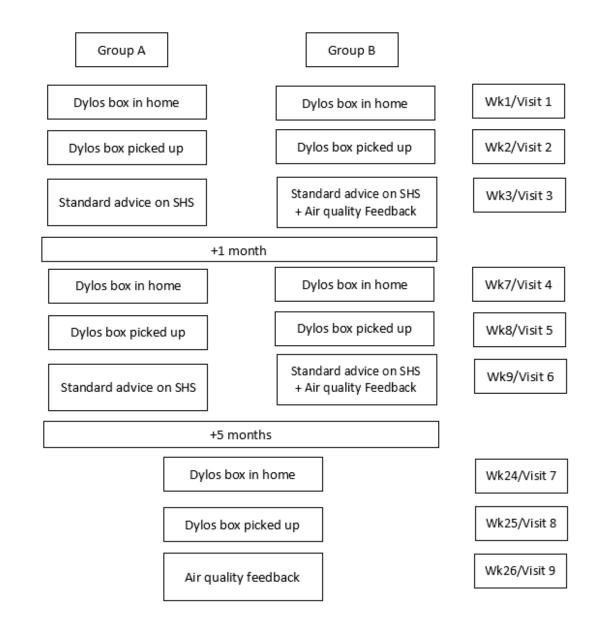
Project home visits were built into the existing FS programme of weekly contacts with clients. Full engagement over the 6-month period involved nine visits where study materials were used. Figure 1 shows the overall research design. In summary, both

groups had PM_{2.5} measurements made in their homes at three time points: baseline, onemonth after they received the intervention and then at approximately six months post intervention. Group A participants received standard UK National Health Service (NHS) advice on the harmful effects of SHS delivered as 'very brief advice' similar to that recommended by the UK National Centre for Smoking Cessation and Training, after the baseline measurement (visit 3 – week 3) and again at follow-up (visit 6 – approximately week 9). Group B participants received this same standard NHS SHS advice but additionally received personalised air-quality feedback at the baseline measurement and follow-up visits. FSP

Feedback of personalised air-quality measurements involved 1-to-1 discussion between the FSP worker and mother using a simple 4-page pamphlet which included: their airquality feedback graph showing temporal changes in PM_{2.5} concentrations over the measurement period; summary quantitative information on the air-quality measurements in their home; information on the effects of SHS; and practical advice on how to reduce SHS. The feedback included information on the proportion of time when household PM_{2.5} concentrations exceeded the World Health Organisation (WHO) guidance value of 25µg/m³ as a health-based air quality benchmark [24]. The air quality feedback pamphlet was produced by the FSP administrator and provided to the participant usually within one week of the measurements having taken place. Feedback was provided to Group B at visit 3 (week 3 after recruitment), again at visit 6 (approximately week 9), and finally at visit 9 (approximately week 26). Group A received all their air quality feedback only on conclusion of their involvement, at visit 9 (week 26). is an early intervention programme provided by the National Health Service in Lanarkshire, Scotland. FSP provides vulnerable first-time mums with intensive, free, one-to-one support during and after pregnancy to give their babies the best possible start in life. Support includes considering the child's exposure to SHS and where appropriate exploring options to reduce this. Over 30% of mothers involved in the programme are smokers with 48% of homes having one or more smoking adult resident.

1.3. Training

Seventeen FSP workers who delivered the intervention received a half-day training course which included: Good Clinical Practice; the health effects of SHS; the recruitment process; using the Air Quality Monitor; and how to discuss the measurements with mothers to encourage them to make their homes smoke-free. The FSP administrator (TH) was trained in downloading data from air-quality instruments and preparing personalised feedback graphs using Microsoft Excel.



1.4. $PM_{2.5}$ measurements

A Dylos DC1700 Air Quality Monitor (Dylos Inc, CA, USA) was installed in the main living_-room of participants' homes to measure $PM_{2.5}$ in the home for 3-7 days on three occasions (baseline, +1 month <u>post-intervention</u>, +6 months <u>post-intervention</u>). <u>The</u> <u>living-room was selected as the area of the home where the family will spend most of</u> their waking hours within the home setting. There is also recent evidence that livingroom and child's bedroom concentrations of air nicotine are well correlated [25]. The Dylos is a low-cost instrument that has been utilised by several research groups to provide real-time data on $PM_{2.5}$ as a proxy for SHS concentrations-[19,264]. It is a simple laser-based particle counter that has been shown to provide data on SHS aerosol that is broadly comparable with data provided by 'gold-standard' optical particle counting instruments-[275]. It costs approximately £300 (US \$400); has near-silent operation and is simple to install and activate to logging mode with a single press of one button.

1.5. SHS feedback

Feedback of personalised air-quality measurements involved 1-to-1 discussion between the FSP worker and mother using a simple 4-page pamphlet which included: their airquality feedback graph showing temporal changes in PM_{2.5} concentrations over the measurement period; summary quantitative information on the air-quality measurements in their home; information on the effects of SHS; and practical advice on how to reduce SHS. This pamphlet was produced by the FSP administrator and provided to the participant usually within one week of the measurements having taken place.

<u>1.6.1.5.</u> *Power calculation and sample size*

Using air-quality at 1-month as our primary outcome measure the study was powered (>80% power with alpha level of 0.05) to detect a difference of at least 30% between groups. To achieve this power we sought to recruit 120 participants to have approximately 50 participants in each arm at the 1-month follow-up stage.

<u>1.7.1.6.</u> *Analysis*

The data from each instrument was downloaded using proprietary software (Dylos Logger (v1.6) and exported to Microsoft Excel to allow temporal analysis and production of graphical feedback. Particle number concentrations were converted to mass concentrations using a previously validated method-[275]. For each sampling period in each household a customized Excel spreadsheet was used to produce summary statistics of $PM_{2.5}$ concentrations including the mean, the peak value, and the percentage of measurement time the instrument recorded values above thresholds. Differences in characteristics between groups and between baseline and follow-up $PM_{2.5}$ mean concentrations were analysed using IBM SPSS (v23) using Student's t-tests for continuous variables and Pearson's Chi Square for categorial variables. Statistical significance was set at p<0.05.

2. Results

2.1. Recruitment

Recruitment took place between June 2014 and February 2016. 171 mothers enrolled in the FSP were invited to take part, of which 120 agreed (response rate 70.2%). Of these, 117 completed baseline measurements, 59 in Group A and 58 in Group B. 102 completed the 1-month follow-up with 78 completing the 6-month stage. Characteristics of the participants are provided in Table 1. Reflecting the population of young, vulnerable mothers that this cohort was drawn from, participants' median and Inter-Quartile Range (IQR) age was 21 (19-23) with 54% of participants living in areas in the bottom 20% in the Scottish Index of Multiple Deprivation (SIMD). Approximately two-thirds (69%) were smokers and three-quarters lived in a flat or tenement (72%), with 1 in 3 reporting no access to private or shared garden space (33%). The only statistical difference between the two groups was that participants in the standard care group (A) were more likely to be pregnant at the time of recruitment. Table 1: Characteristics of study participants [Group A = standard care; Group B =

standard care plus air quality leedback	ndard care plus air quality feed	dback]	
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	Overall	Group A	Group B	p value
Number of participants	117	59	58	I
Age: mean (range) in years	21.6	21.4	21.7	p= 0.666
	(17-43)	(17-38)	(17-43)	1
SIMD [#] : mean (range)	2.8	2.7	3.0	p= 0.449
	(1-10)	(1-7)	(1-10)	-
Smokers	81 (69%)	36 (61%)	45 (76%)	p= 0.071
Pregnant	29%	37%	21%	p= 0.048
Garden space available	67%	75%	64%	p= 0.106
Self-report smoke-free home at	27%	23%	32%	p= 0.270
baseline				
Baseline measurement	7890	7956	7824	p= 0.709
duration: mean (range) in	(2213-9056)	(2213-9056)	(2237-9056)	
minutes				
Baseline PM _{2.5} average: mean	67.5	73.4	61.4	<mark>₽</mark> =0.418
(range) in $\mu g/m^3$	(4.5-424)	(4.5-424)	(5.1-295)	
Baseline PM _{2.5} peak [^] : mean	547	558	537	<mark>₽</mark> =0.678
(range) in $\mu g/m^3$	(48.3-1126)	(48.3-1105)	(63-1126)	
Baseline $PM_{2.5}$ % time >25	40.0	39.0	38.9	p= 0.984
μg/m ³ : mean (range)*	(1-100)	(1-100)	(1-100)	

[#] The Scottish Index for Multiple Deprivation decile (A score of 1 is the 10% most deprived; 10 is the 10% most affluent)

^ The peak exposure refers to the highest 1-minute concentration recorded in the home.

* The 25 μ g/m³ threshold is used as a marker of the proportion of time where the household PM_{2.5} concentration exceeded the World Health Organisation 24h guidance value [2<u>46</u>] for fine particulate pollution.

2.2. *Air quality results*

A total of 2,278,614 minutes of valid air-quality data was obtained from 297 visits to

participants' homes. Table 1 provides a breakdown of household PM_{2.5} measurements

made at baseline including the household average, peak and percentage of time

measurements were above the WHO 24-hour guidance value (25 μ g/m³)-[246].

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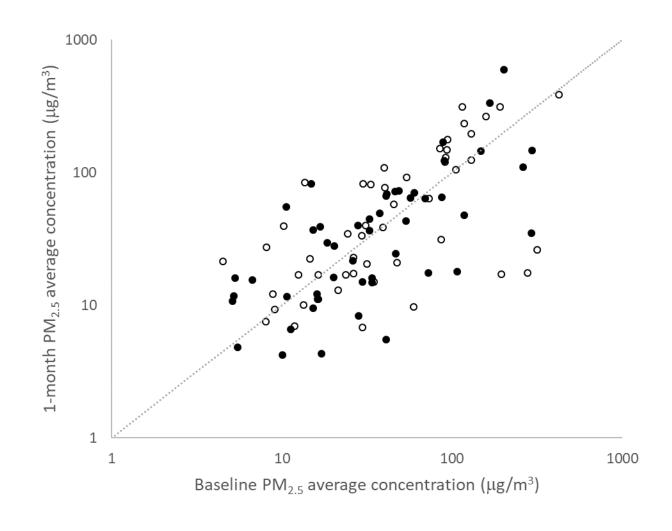
After excluding participants who did not complete the 1-month follow up or for whom the measurement duration at the follow-up visit was <24 hours (n=2 at 1-month; n=1 at 6months) the median (95% Confidence Interval)IQR) difference between 1-month and baseline PM_{2.5} measurements for Group A (n=50) was +3.8 (-16.439.1 to; 28.8-8.4); Group B (n=50) was 10.1 (-22.3 to11.8 24.5, -14.7) μ g/m³ (p=0.76 for comparison). Similar results were found for comparison between the 6-month and baseline PM_{2.5} measurements, with Group A (n=40) -1.7 (-18.3 to 4.526.5, 8.8); Group B (n=37) -1.0 (-8.1 to21.211.4, -16.2) μ g/m³ (p=0.16). A similar pattern was found when the change was expressed as a percentage change relative to the baseline measurement to account for the variation in measured concentrations at baseline. Table 2 provides these data in summary form. Figure 2 illustrates this change by paired measurements for each home with each data point providing the baseline and 1-month follow-up average PM_{2.5} concentrations measured.

Table 2: Change in $PM_{2.5}$ between baseline and +1 and +6 month follow-up. Expressed as an absolute change and as a percentage of the baseline measurement. [Group A = standard care; Group B = standard care plus air quality feedback]

	Baseline to +1 change	month	Baseline to +6 months change		
Allocation group	Α	B	Α	В	
Number of participants	50	50	40	37	
Change in average $PM_{2.5} \mu g/m^3$:	+3.8	+1.1	-1.7	-1.0	
median and 95% Confidence	(-16.4 to	(-22.3 to	(-18.3 to	(-8.1 to	
Interval	28.8)	24.5)	4.5)	11.4)	
Change in average $PM_{2.5}$ as a	+20%	+3%	-8%	-6%	
percentage of baseline	(-6 to 43)	(-24 to 36)	(-34 to 13)	(-27 to	
measurement: median and 95%				40)	

Confidence Interval

Figure 2: Scatterplot illustrating the paired $PM_{2.5}$ average values from each home measured at baseline and the<u>n</u> again at +1 month, divided by allocation group (A group = clear circles; B group = black circles). The black 1:1 line represents zero change; points to the left of the line indicate an increase in SHS levels after 1 month and points to the right of the line indicate homes that had reduced SHS levels after 1 month.



The baseline $PM_{2.5}$ concentrations from homes where the participants self-reported having a smoke-free home at baseline (i.e. responded positively to the statement that 'Smoking is not allowed inside your home') (n=31) was found to be significantly lower than those who confirmed smoking (n=82) was allowed in the home. The median and (95% CI) value was 14.9 (10.7-20.8) compared to 48.2 (39.3-75.3) µg/m³. Analysis was also carried out after excluding these 31 self-reported smoke-free homes (at baseline) but the lack of significant change and similarity in response between the intervention groups was maintained.

2.3. Self-reported changes in household smoking

Questionnaires were completed by 114 participants at baseline; 95 at 1-month and 72 at 6-month stages. Not all participants provided a response to all questions. At 1-month 10/47 Group A participants reported becoming a 'smoke-free' home compared to 12/45 in Group B (Pearson's Chi-square = 0.205). Similar changes were noted at 1-month in self-reported quitting (4 from Group A and 2 from Group B) or self-reported reduction in smoking (6 from Group A and 10 from Group B). At 1-month, reported smoking by the participant 'in the presence of children inside the home' was reduced for 5/46 participants in Group A and 5/47 in Group B (none reported smoking 'more than before') (p=0.284). Similarly, 8/44 (Group A) and 7/48 (Group B) participants reported other smoking adults in the home 'smoking less than before' in the presence of children at 1-month follow-up (p=0.307).

3. Discussion

This study is the first to trial the use of air-quality feedback as an intervention to encourage smoke-free homes delivered in a real-world setting as part of health professionals' routine work with smoking clients. The study demonstrated that measurement of household air quality and personalised feedback of results to a group of disadvantaged mothers of young children was achievable at scale and could be incorporated by health professionals within existing health care services provided to parents. Recruitment was high with over 70% of eligible mothers agreeing to participate in the study, indicating a high level of interest in receiving this type of individual data about SHS concentrations in the home. Follow-up participation was also good with over 87% of those who completed the baseline measurements taking part at 1-month, and 67%at 6-month follow-up. However, this adequately powered RCT using an objective measurement of smoke-free status (PM_{25}) found that home SHS levels did not change in either arm of the trial. Whilst $PM_{2.5}$ feedback has proven effective in reducing household SHS concentrations after selection from the general population, this study indicates that different strategies may be required for vulnerable families such as those included in this trial.

The practicalities of delivering the intervention generally worked well despite the complexities of: installing the device three times per household; collecting one-week later; having the data downloaded and the feedback pamphlet generated centrally by one FSP administrator; and meeting with the participant as soon as possible thereafter. Logistical difficulties highlighted by the FSP workers and administrator included: the

length of time it took to download the data; the need to prepare hard-copies of feedback reports in colour (FSP workers did not have local printing facilities); liaison with FSP workers who had substantial caseloads and covered large geographical areas.

The pre-intervention baseline household $PM_{2.5}$ concentrations showed broadly similar median (34 µg/m³) and IQR (16-88 µg/m³) values to those previously reported in other Scottish homes where smoking is permitted (median 31 µg/m³; IQR (10-111 µg/m³)):[7]. At baseline nearly two-thirds of homes (64.1%) had average $PM_{2.5}$ concentrations greater than the WHO guidance value for 24-hour average exposure (25 µg/m³) with 1 in 5 (20.5%) showing average values greater than 100 µg/m³. It is worth considering that these 24-hour $PM_{2.5}$ levels would generate considerable media attention if they were present in outdoor air in urban environments. Indeed, these data suggest that fine particulate air pollution is greater than the annual average $PM_{2.5}$ concentration in Beijing (51 µg/m³)[2<u>8</u>7] one of the most polluted cities in the world, in about one-third of the homes that took part in this study.

These results can be compared to other studies that have used personalised air quality feedback, albeit from different populations. The REFRESH study recruited 59 smoking mothers in Scotland and provided $PM_{2.5}$ measurement data over a 24-hour period as the primary tool in a motivational interview aimed at empowering parents to make their home smoke-free [17]. That study found that mothers who received air-quality feedback reduced $PM_{2.5}$ concentrations by approximately one-third although the study was too small to detect a difference with the control group. More recent work by Ratschen and

colleagues [18] studied a similar approach with disadvantaged smoking parents in Nottingham. That study compared a complex intervention combining personalised air quality feedback, behavioural support and nicotine replacement therapy for temporary abstinence with usual care involving standard advice. The 24h PM_{2.5} concentration in intervention homes reduced exposure about one-third at the 12-week follow-up. Hughes et al [19] have reported an intervention involving an air-quality instrument with warning lights and alarms to provide real-time feedback on particle concentrations in smokers' home. Their work showed an average reduction of approximately 19% in households receiving this feedback compared to just 6.5% reduction in control homes. From the REFRESH study [17] and more recent work in Nottingham [18] those mothers who received personalised air-quality feedback had average reductions in household PM_{2.5}-concentrations of about 30%. The change was not statistically significant in the REFRESH study given the small sample size and, in this respect, the present findings are similar.

The reasons for the lack of change in PM_{2.5} concentrations in the current study are unclear but may involve the disadvantages experienced by this group and include the dual barriers of a lack of opportunity to make changes and lack of support from other smoking adults. Qualitative interviews carried out with a selection of study participants [298] demonstrated that the intervention increased mothers' capability to change smoking behavior in the home, through better awareness of the risks to their children from SHS exposure. However, taking significant action was often constrained by their limited, and often changing, social and environmental opportunities, including smoking of other adults in the home setting. Recent work on the barriers, motivators and enablers to creating a smoke-free home have shown the complex interplay that exists in many homes can make the process difficult_:[3029-310].

The intervention was based on review of behavioural interventions to reduce indoor smoking by parents which led to the development of the AFRESH behavior theory programme described in detail elsewhere-.[32]+]. Review of the literature indicated that incorporating objectively assessed feedback data and motivational interviewing appear to be the most popular adopted intervention methods and the most effective for SHS reduction with parents and caregivers of young children. Simply providing written information about the risks of SHS is not an effective strategy for this specific behaviour change type and instead ongoing support and interaction may play a vital role in the success of such SHS reduction interventions. The review also identified that it is necessary to strike a balance between making the intervention intensive enough to be effective but also ensuring too many sessions are not required, as the target population (often socioeconomically disadvantaged people) may find multiple session attendance problematic.

3.1. Strengths and limitations

In addition to the objective assessment of air-quality in each home, a particular strength of the study over other previous work was the duration of measurements. Air-quality data were collected for an average of 127 hours (5.3 days) during each stage in each home. In addition to the potential bias from the Hawthorne effect during short measurement periods, [332], FSP workers reported that household activity (number of adults, number of cigarettes smoked, hours spent indoors etc.) was often highly variable due to complex issues around substance misuse, unemployment and changing relationships. There is significant potential to misclassify household concentrations of SHS through the use of snapshot or even 24h measurement of PM_{2.5} and longer duration measurement reduces the chance of people changing their behaviour whilst measurements are being made. Gathering data over 3-7 days is likely to have reduced these potential biases and provided a more accurate picture of SHS concentrations within each home at baseline and followup.

There were several limitations mostly due to the delivery challenges of real-world settings, structures and events. For example, a small number of participants moved home during the 6-months and so measurements were not always taken in the same setting. Similarly, partners or other adults living in the home sometimes changed between baseline and follow-up and so conditions were not always directly comparable. The intervention was delivered by 17 FSP workers and while all received identical training, the type of feedback and advice received by participants may have differed. The intervention was intentionally delivered as part of an existing relationship between the participant and their FSP worker, and possibly pre-existing differences in those relationships may have influenced the way the information was received and acted on.

In a few cases devices were switched off for periods of time during measurements. This was sometimes due to interruptions in electricity supply or may have been due to participants/others in the home deciding to switch the device off because of the desire to prevent the device measuring high levels of SHS during smoking. However, compliance was high with the number and duration of periods of lost data small in comparison to the time instruments were in homes. There was no evidence that data loss was more frequent at follow-up than baseline and so we do not think this had a significant impact on our results.

A further limitation of the study is the use of $PM_{2.5}$ as a marker for SHS. While this method has been used extensively in tobacco control research as a means of quantifying SHS concentrations;[14-16], $PM_{2.5}$ is not specific to tobacco smoke and can arise from non-smoking sources such as ambient air pollution, cooking and use of solid fuels. While it is possible that some increases of $PM_{2.5}$ may have been due to non-smoking activity (particularly frying of food), it is also possible that smoking may have continued in these homes during periods when the participant was unaware of the behaviour of (other) smoking adults. We believe that our $PM_{2.5}$ measurements are likely to provide robust information on household SHS data and e note data from the Scottish Government ambient air quality monitor located in Hamilton, the administrative centre of the Lanarkshire area, that shows low PM concentrations and no discernible seasonal variation with monthly average PM_{10} concentrations across 2015 ranging from 14 to 21 µg/m³ ($PM_{2.5}$ is typically about 60% the value of PM_{10}) [34-35] and d-draw on $PM_{2.5}$ concentration data gathered from previous studies in Scotland that showed average

concentrations in typical smoke-free homes were 3 μg/m³ [7] and 8-16 μg/m³ even when combustion sources such as coal, wood and gas were used for heating or cooking purposes₇[3<u>6</u>3]. While measurement of air nicotine would provide a tobacco-specific method of quantifying SHS concentrations, this approach would currently not provide time-resolved information and would require expensive (and slow) chemical laboratory analysis: something that is likely to be a barrier to any future use of this intervention approach. New technologies under development may provide real-time nicotine concentrations using low-cost methods [34<u>7</u>] or utilise data on particle size distributions from different emission sources to differentiate SHS from other household aerosols -[3<u>8</u>5]. Work on using the differential response of the Dylos to fine and coarse PM to identify SHS from other aerosols may also provide a way forward in quantifying the contribution of smoking to indoor air pollution-[<u>326]</u>.

The intervention method used delayed feedback of air quality data and provided this feedback only once at baseline and again at the one-month follow-up. It was necessary to take the device back to the office to perform the download and generation of the graphical and numerical feedback. This meant that feedback was typically provided one week after completion of the measurement period. There is evidence that rapid feedback is more effective in eliciting change in health and safety behaviors [4037] and future work should examine methods to provide more immediate feedback to those engaging in smoke-free home interventions. Providing air quality feedback on just a single occasion (prior to the follow-up assessment) may be another reason that the study showed no effect on those receiving the intervention. Work by Klepeis and colleagues has begun to explore the use of warning lights and alarms on air quality monitors used to measure SHS_-[264]. Our group has also recently initiated a study to examine SHS concentration feedback using a Dylos connected to the internet to upload data in real-time to then provide participants with mobile phone SMS, email and telephone feedback and guidance [ClinicalTrials.gov Identifier: NCT03151421].

It is also possible that the intervention was not sufficiently strong to change behavior in a sustained manner. There is evidence from the literature on health warnings that 'shock' is often short-lived and does not produce long-term changes in smoking behavior_-[4138]. This may be particularly true if there are significant barriers to enacting change and the subject has limited capacity to change: the single parent caring for a young child in a high-rise flat has fewer options in terms of modifying their smoking behavior compared to someone living with a partner in a ground floor home with access to garden space.

We also note that the current best practice of offering standard NHS advice on the health harms of SHS produced reductions in PM_{2.5} concentration in the control arm of the study. We are not aware of any studies that have evaluated the effectiveness of 'standard' or 'very brief advice' on SHS from Health Professionals to smoking parents and recommend that future work looks at how this can be improved and better targeted to help protect children from SHS at home.

The FSP provides support to young mothers and the intervention was therefore targeted at this group despite the fact that other adults (partners, parents, visitors) may be smokers in the home. While the intervention hoped to provide mothers with the motivation and tools to engage with other adult smokers this is very likely to be subject to differences in family dynamics and social circumstances. Future work should consider an 'all household' approach where the intervention is delivered to all those who smoke in the home and have an interest in the child's health -[4239].

3.2. Conclusions

Personalised feedback of air-quality information using low-cost devices can be successfully integrated into routine services provided by health care providers. The overall results show that, in this group of disadvantaged mothers, there was no change in household SHS concentrations after delivery of the intervention. On this basis it seems unlikely that personalised air-quality feedback is sufficient, in itself, to change smoking behaviour in disadvantaged households in Scotland and similar countries where there is already a high awareness of the risks of SHS. Providing personalised air-quality feedback may not be suitable for all groups of smoking parents and may instead need to be tailored to those at a more advanced stage of change in terms of household smoking rules and, importantly, with the physical and social opportunities to change. Further work is required to identify the types of smoking households where air-quality feedback can play a role in supporting parents to protect their children from SHS. More immediate feedback methods delivered to all adults in the home may be key to achieving sustained household behavior change in relation to smoking.

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1570	
1571	Competing interests
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1573	None of the authors have any competing interests.
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1587	Contribution statement
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1591	SM and LA managed the FSP workers and the collection of the data; TH carried out the
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1593	production of the air-quality feedback for each participant. SS analysed the data, wrote
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1595	the first draft of the manuscript and is the guarantor for this study. All authors made
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1597	contributions to and approved the final manuscript.
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Highlights

- Health professionals can successfully deliver personalized air quality information in home settings
- We found no evidence that air-quality feedback helps create a smoke-free home
- Finding parents for whom this intervention may work requires a targeted approach

Abstract

Objective: To determine if low-cost air-quality monitors providing personalised feedback of household second-hand smoke (SHS) concentrations plus standard health service advice on SHS were more effective than standard advice in helping parents protect their child from SHS.

Design: A randomised controlled trial of a personalised intervention delivered to disadvantaged mothers who were exposed to SHS at home. Changes in household concentrations of fine Particulate Matter ($PM_{2.5}$) were the primary outcome.

Methods: Air-quality monitors measured household PM_{2.5} concentrations over approximately 6 days at baseline and at one-month and six-months post-intervention. Data on smoking and smoking-rules were gathered. Participants were randomised to either Group A (standard health service advice on SHS) or Group B (standard advice plus personalised air-quality feedback). Group B participants received personalised air-quality feedback after the baseline measurement and at 1-month. Both groups received air-quality feedback at 6-months.

Results: 120 mothers were recruited of whom 117 were randomised. Follow up was completed after 1-month in 102 and at 6-months in 78 participants. There was no statistically significant reduction in $PM_{2.5}$ concentrations by either intervention type at 1-month or 6-months, nor significant differences between the two groups at 1-month (p=0.76) and 6-month follow-up (p=0.16).

Conclusions: Neither standard advice nor standard advice plus personalised air-quality feedback were effective in reducing $PM_{2.5}$ concentrations in deprived households where

smoking occurred. Finding ways of identifying homes where air-quality feedback can be a useful tool to change household smoking behaviour is important to ensure resources are targeted successfully.

Using air-quality feedback to encourage disadvantaged parents to create a smokefree home: results from a randomised controlled trial

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Keywords: Environmental Tobacco Smoke, Second-hand Smoke, Children, PM_{2.5}, Education, Intervention

1. Introduction

Second-hand tobacco smoke (SHS) is a common indoor air pollutant linked to a wide range of respiratory[1-2], cardiovascular [3] and early life ill-health effects[4], with exposure more common in disadvantaged households[5]. Non-smokers who live with smokers can have high SHS exposures, particularly young children who spend much of their day at home with a smoker[6-7]. Globally it is estimated that 40% of children experience regular exposure to SHS with much of this exposure occurring in their own home[8]. The global burden of this exposure is estimated to be over 600,000 deaths and almost 11 million disability-adjusted life-years per year. Children are particularly vulnerable to the effects of SHS exposure and suffer 28% of these deaths and 61% of this morbidity[9].

Enabling parents to create a smoke-free home is challenging but it is one of the key ways that children's exposure to SHS can be reduced globally. Scotland is at the forefront of protecting children from exposure to SHS with the Scottish Government's 'Take it Right Outside' campaign including a world first: a governmental target to reduce the proportion of children exposed to SHS at home by 50% (from 12% to 6%) by 2020[10]. Increased adoption of smoke-free homes in low income populations has also been shown to increase cessation rates and prevent relapse[11]. There is a need for good quality evidence on ways to increase the proportion of smoke-free homes in different settings. The most recent Cochrane review [12] of programmes to reduce children's exposure to SHS screened 57 relevant studies but identified that only 6 used objective measures of children's SHS exposure to evaluate intervention effectiveness. None of the included

studies used air-quality feedback. A recent systematic review and meta-analysis [13] identified seven interventions designed to encourage smoke-free homes that had used objective measures of household air quality as an outcome measure. The meta-analysis indicated that these approaches generally had an impact on reducing air concentrations of fine particulate matter (PM_{2.5}) or nicotine within the household; though all studies reported evidence of continuing SHS 'contamination' post-intervention.

Methods to measure SHS in indoor settings using airborne $PM_{2.5}$ as a marker of SHS concentrations have been used in tobacco control science over the past decade[14-16]. Several studies have explored the concept of air-quality feedback to modify smoking behaviour in the home[17-19].

There are considerable challenges in rolling out this type air-quality feedback intervention at scale. The REFRESH study identified low recruitment rates (when potential participants were approached via GP letter); the high cost of available instruments and technical complexity; and the labour costs of delivering, setting up and collecting instruments from participants' homes[20]. Recent work has identified low-cost air-quality monitoring devices that have the potential to address the practical problems of noise, cost and complexity of operation identified in previous studies[21].

The aim of the study was to determine if delivery of personalised air-quality feedback plus standard advice on the health effects of SHS was more effective than standard advice on its own in encouraging changes to household smoking as measured by objective assessment of PM_{2.5} concentrations one-month later. The study was nested within the

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282	
283	First Steps Programme (FSP) in Lanarkshire in Scotland [22], providing an opportunity
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285	to overcome many of the barriers identified in the REFRESH study [23] in terms of
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287	recruiting disadvantaged parents, embedding the intervention within an existing service
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Methods

1.1. Study design

This was a randomised controlled trial which compared standard advice to achieve a smoke-free home against standard advice plus personalised air-quality feedback. Vulnerable mothers who smoked or lived with smokers and were engaged with the Lanarkshire FSP were eligible. FSP is an early intervention programme provided by the National Health Service in Lanarkshire, Scotland, providing vulnerable first-time mums with intensive, free, one-to-one support during and after pregnancy to give their babies the best possible start in life. Support includes considering the child's exposure to SHS and where appropriate exploring options to reduce this. Over 30% of mothers involved in the programme are smokers with 48% of homes having one or more smoking adult resident.

First Steps (FS) workers identified clients who were thought likely to have SHS exposure in the home either from self-report of household smoking or observations of the presence of SHS within the home. Participants were excluded from the study if they were: under 16; they were unable to give informed consent due to physical or mental incapacity; or there was no smoker resident within the household. Information sheets were provided and written informed consent gained. Participants were randomised to group A or B by a member of the research team blind to the participants' details, using the ID number and randomisation function in Microsoft Excel. A short baseline questionnaire was completed to determine self-reported current smoking, household smoking rules and attitudes towards smoking.

Questionnaires assessed changes in smoking, household rules and quit attempts at the 1and 6-month follow-ups. All study participants received a £10 shopping voucher on completing the baseline and a further £20 on completion of the 6-month follow-up visit. The primary outcome was change in the household PM_{2.5} concentration after one month. Ethical approval for the study was obtained from the NHS North of Scotland Research Ethics Committee (REC reference: 14/NS/0030; Protocol number: 2/012/14; IRAS project ID: 150095).

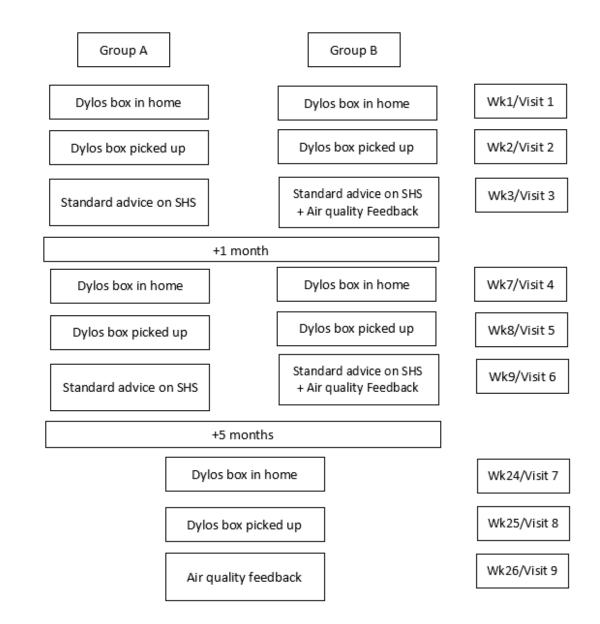
1.2. Intervention

Project home visits were built into the existing FS programme of weekly contacts with clients. Full engagement over the 6-month period involved nine visits where study materials were used. Figure 1 shows the overall research design. In summary, both groups had PM_{2.5} measurements made in their homes at three time points: baseline, one-month after they received the intervention and then at approximately six months post intervention. Group A participants received standard UK National Health Service (NHS) advice on the harmful effects of SHS delivered as 'very brief advice' similar to that recommended by the UK National Centre for Smoking Cessation and Training, after the baseline measurement (visit 3 – week 3) and again at follow-up (visit 6 – approximately week 9). Group B participants received this same standard NHS SHS advice but additionally received personalised air-quality feedback at the baseline measurement and follow-up visits.

Feedback of personalised air-quality measurements involved 1-to-1 discussion between the FSP worker and mother using a simple 4-page pamphlet which included: their airquality feedback graph showing temporal changes in PM_{2.5} concentrations over the measurement period; summary quantitative information on the air-quality measurements in their home; information on the effects of SHS; and practical advice on how to reduce SHS. The feedback included information on the proportion of time when household PM_{2.5} concentrations exceeded the World Health Organisation (WHO) guidance value of 25μg/m³ as a health-based air quality benchmark [24]. The air quality feedback pamphlet was produced by the FSP administrator and provided to the participant usually within one week of the measurements having taken place. Feedback was provided to Group B at visit 3 (week 3 after recruitment), again at visit 6 (approximately week 9), and finally at visit 9 (approximately week 26). Group A received all their air quality feedback only on conclusion of their involvement, at visit 9 (week 26).

1.3. Training

Seventeen FSP workers who delivered the intervention received a half-day training course which included: Good Clinical Practice; the health effects of SHS; the recruitment process; using the Air Quality Monitor; and how to discuss the measurements with mothers to encourage them to make their homes smoke-free. The FSP administrator (TH) was trained in downloading data from air-quality instruments and preparing personalised feedback graphs using Microsoft Excel.



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1.4. $PM_{2.5}$ measurements

A Dylos DC1700 Air Quality Monitor (Dylos Inc, CA, USA) was installed in the main living-room of participants' homes to measure $PM_{2.5}$ in the home for 3-7 days on three occasions (baseline, +1 month post-intervention, +6 months post-intervention). The living-room was selected as the area of the home where the family will spend most of their waking hours within the home setting. There is also recent evidence that livingroom and child's bedroom concentrations of air nicotine are well correlated [25]. The Dylos is a low-cost instrument that has been utilised by several research groups to provide real-time data on $PM_{2.5}$ as a proxy for SHS concentrations[19,26]. It is a simple laser-based particle counter that has been shown to provide data on SHS aerosol that is broadly comparable with data provided by 'gold-standard' optical particle counting instruments[27]. It costs approximately £300 (US \$400); has near-silent operation and is simple to install and activate to logging mode with a single press of one button.

1.5. Power calculation and sample size

Using air-quality at 1-month as our primary outcome measure the study was powered (>80% power with alpha level of 0.05) to detect a difference of at least 30% between groups. To achieve this power we sought to recruit 120 participants to have approximately 50 participants in each arm at the 1-month follow-up stage.

1.6. Analysis

The data from each instrument was downloaded using proprietary software (Dylos Logger (v1.6) and exported to Microsoft Excel to allow temporal analysis and production of graphical feedback. Particle number concentrations were converted to mass concentrations using a previously validated method[27]. For each sampling period in each household a customized Excel spreadsheet was used to produce summary statistics of $PM_{2.5}$ concentrations including the mean, the peak value, and the percentage of measurement time the instrument recorded values above thresholds. Differences in characteristics between groups and between baseline and follow-up $PM_{2.5}$ mean concentrations were analysed using IBM SPSS (v23) using Student's t-tests for continuous variables and Pearson's Chi Square for categorial variables. Statistical significance was set at p<0.05.

2. Results

2.1. Recruitment

Recruitment took place between June 2014 and February 2016. 171 mothers enrolled in the FSP were invited to take part, of which 120 agreed (response rate 70.2%). Of these, 117 completed baseline measurements, 59 in Group A and 58 in Group B. 102 completed the 1-month follow-up with 78 completing the 6-month stage. Characteristics of the participants are provided in Table 1. Reflecting the population of young, vulnerable mothers that this cohort was drawn from, participants' median and Inter-Quartile Range (IQR) age was 21 (19-23) with 54% of participants living in areas in the bottom 20% in the Scottish Index of Multiple Deprivation (SIMD). Approximately two-thirds (69%) were smokers and three-quarters lived in a flat or tenement (72%), with 1 in 3 reporting no access to private or shared garden space (33%). The only statistical difference between the two groups was that participants in the standard care group (A) were more likely to be pregnant at the time of recruitment. Table 1: Characteristics of study participants [Group A = standard care; Group B =

	Overall	Group A	Group B	p value
Number of participants	117	59	58	
Age: mean (range) in years	21.6	21.4	21.7	0.666
	(17-43)	(17-38)	(17-43)	
SIMD [#] : mean (range)	2.8	2.7	3.0	0.449
	(1-10)	(1-7)	(1-10)	
Smokers	81 (69%)	36 (61%)	45 (76%)	0.071
Pregnant	29%	37%	21%	0.048
Garden space available	67%	75%	64%	0.106
Self-report smoke-free home at	27%	23%	32%	0.270
baseline				
Baseline measurement	7890	7956	7824	0.709
duration: mean (range) in	(2213-9056)	(2213-9056)	(2237-9056)	
minutes				
Baseline PM _{2.5} average: mean	67.5	73.4	61.4	0.418
(range) in $\mu g/m^3$	(4.5-424)	(4.5-424)	(5.1-295)	
Baseline PM _{2.5} peak [^] : mean	547	558	537	0.678
(range) in $\mu g/m^3$	(48.3-1126)	(48.3-1105)	(63-1126)	
Baseline $PM_{2.5}$ % time >25	40.0	39.0	38.9	0.984
$\mu g/m^3$: mean (range)*	(1-100)	(1-100)	(1-100)	

standard care plus air quality feedback]

[#] The Scottish Index for Multiple Deprivation decile (A score of 1 is the 10% most deprived; 10 is the 10% most affluent)

^ The peak exposure refers to the highest 1-minute concentration recorded in the home.

* The 25 μ g/m³ threshold is used as a marker of the proportion of time where the household PM_{2.5} concentration exceeded the World Health Organisation 24h guidance value [24] for fine particulate pollution.

2.2. *Air quality results*

A total of 2,278,614 minutes of valid air-quality data was obtained from 297 visits to

participants' homes. Table 1 provides a breakdown of household PM2.5 measurements

made at baseline including the household average, peak and percentage of time

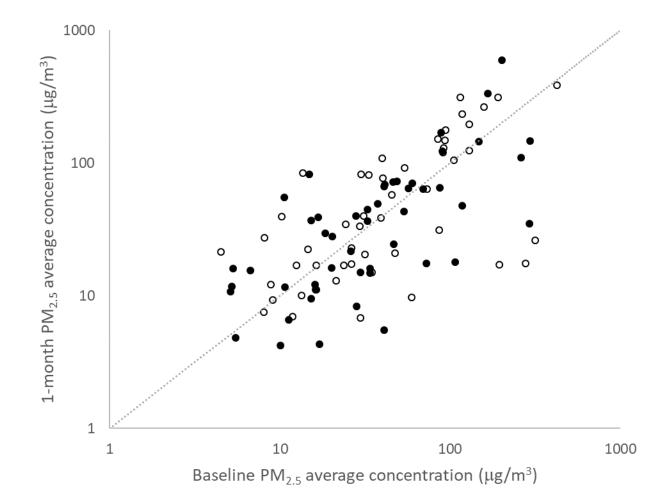
measurements were above the WHO 24-hour guidance value $(25 \ \mu g/m^3)[24]$.

After excluding participants who did not complete the 1-month follow up or for whom the measurement duration at the follow-up visit was <24 hours (n=2 at 1-month; n=1 at 6months) the median (95% Confidence Interval) difference between 1-month and baseline $PM_{2.5}$ measurements for Group A (n=50) was +3.8 (-16.4 to 28.8); Group B (n=50) was 1.1 (-22.3 to 24.5) µg/m³ (p=0.76 for comparison). Similar results were found for comparison between the 6-month and baseline $PM_{2.5}$ measurements, with Group A (n=40) -1.7 (-18.3 to 4.5); Group B (n=37) -1.0 (-8.1 to11.4) µg/m³ (p=0.16). A similar pattern was found when the change was expressed as a percentage change relative to the baseline measurement to account for the variation in measured concentrations at baseline. Table 2 provides these data in summary form. Figure 2 illustrates this change by paired measurements for each home with each data point providing the baseline and 1-month follow-up average $PM_{2.5}$ concentrations measured.

Table 2: Change in $PM_{2.5}$ between baseline and +1 and +6 month follow-up. Expressed as an absolute change and as a percentage of the baseline measurement. [Group A = standard care; Group B = standard care plus air quality feedback]

	Baseline to +1 change	month	Baseline to +6 months change	
Allocation group	A	В	A	В
Number of participants	50	50	40	37
Change in average $PM_{2.5} \mu g/m^3$:	+3.8	+1.1	-1.7	-1.0
median and 95% Confidence	(-16.4 to	(-22.3 to	(-18.3 to	(-8.1 to
Interval	28.8)	24.5)	4.5)	11.4)
Change in average $PM_{2.5}$ as a	+20%	+3%	-8%	-6%
percentage of baseline	(-6 to 43)	(-24 to 36)	(-34 to 13)	(-27 to
measurement: median and 95%				40)
Confidence Interval				

Figure 2: Scatterplot illustrating the paired $PM_{2.5}$ average values from each home measured at baseline and then again at +1 month, divided by allocation group (A group = clear circles; B group = black circles). The black 1:1 line represents zero change; points to the left of the line indicate an increase in SHS levels after 1 month and points to the right of the line indicate homes that had reduced SHS levels after 1 month.



The baseline $PM_{2.5}$ concentrations from homes where the participants self-reported having a smoke-free home at baseline (i.e. responded positively to the statement that

'Smoking is not allowed inside your home') (n=31) was found to be significantly lower than those who confirmed smoking (n=82) was allowed in the home. The median and (95% CI) value was 14.9 (10.7-20.8) compared to 48.2 (39.3-75.3) μ g/m³. Analysis was also carried out after excluding these 31 self-reported smoke-free homes (at baseline) but the lack of significant change and similarity in response between the intervention groups was maintained.

2.3. Self-reported changes in household smoking

Questionnaires were completed by 114 participants at baseline; 95 at 1-month and 72 at 6-month stages. Not all participants provided a response to all questions. At 1-month 10/47 Group A participants reported becoming a 'smoke-free' home compared to 12/45 in Group B (Pearson's Chi-square = 0.205). Similar changes were noted at 1-month in self-reported quitting (4 from Group A and 2 from Group B) or self-reported reduction in smoking (6 from Group A and 10 from Group B). At 1-month, reported smoking by the participant 'in the presence of children inside the home' was reduced for 5/46 participants in Group A and 5/47 in Group B (none reported smoking 'more than before') (p=0.284). Similarly, 8/44 (Group A) and 7/48 (Group B) participants reported other smoking adults in the home 'smoking less than before' in the presence of children at 1-month follow-up (p=0.307).

This study is the first to trial the use of air-quality feedback as an intervention to encourage smoke-free homes delivered in a real-world setting as part of health professionals' routine work with smoking clients. The study demonstrated that measurement of household air quality and personalised feedback of results to a group of disadvantaged mothers of young children was achievable at scale and could be incorporated by health professionals within existing health care services provided to parents. Recruitment was high with over 70% of eligible mothers agreeing to participate in the study, indicating a high level of interest in receiving this type of individual data about SHS concentrations in the home. Follow-up participation was also good with over 87% of those who completed the baseline measurements taking part at 1-month, and 67%at 6-month follow-up. However, this adequately powered RCT using an objective measurement of smoke-free status (PM_{25}) found that home SHS levels did not change in either arm of the trial. Whilst PM_{25} feedback has proven effective in reducing household SHS concentrations after selection from the general population, this study indicates that different strategies may be required for vulnerable families such as those included in this trial.

The practicalities of delivering the intervention generally worked well despite the complexities of: installing the device three times per household; collecting one-week later; having the data downloaded and the feedback pamphlet generated centrally by one FSP administrator; and meeting with the participant as soon as possible thereafter. Logistical difficulties highlighted by the FSP workers and administrator included: the

The pre-intervention baseline household $PM_{2.5}$ concentrations showed broadly similar median (34 µg/m³) and IQR (16-88 µg/m³) values to those previously reported in other Scottish homes where smoking is permitted (median 31 µg/m³; IQR (10-111 µg/m³))[7]. At baseline nearly two-thirds of homes (64.1%) had average $PM_{2.5}$ concentrations greater than the WHO guidance value for 24-hour average exposure (25 µg/m³) with 1 in 5 (20.5%) showing average values greater than 100 µg/m³. It is worth considering that these 24-hour $PM_{2.5}$ levels would generate considerable media attention if they were present in outdoor air in urban environments. Indeed, these data suggest that fine particulate air pollution is greater than the annual average $PM_{2.5}$ concentration in Beijing (51 µg/m³)[28] one of the most polluted cities in the world, in about one-third of the homes that took part in this study.

These results can be compared to other studies that have used personalised air quality feedback, albeit from different populations. The REFRESH study recruited 59 smoking mothers in Scotland and provided $PM_{2.5}$ measurement data over a 24-hour period as the primary tool in a motivational interview aimed at empowering parents to make their home smoke-free [17]. That study found that mothers who received air-quality feedback reduced $PM_{2.5}$ concentrations by approximately one-third although the study was too small to detect a difference with the control group. More recent work by Ratschen and

colleagues [18] studied a similar approach with disadvantaged smoking parents in Nottingham. That study compared a complex intervention combining personalised air quality feedback, behavioural support and nicotine replacement therapy for temporary abstinence with usual care involving standard advice. The 24h PM_{2.5} concentration in intervention homes reduced exposure about one-third at the 12-week follow-up. Hughes et al [19] have reported an intervention involving an air-quality instrument with warning lights and alarms to provide real-time feedback on particle concentrations in smokers' home. Their work showed an average reduction of approximately 19% in households receiving this feedback compared to just 6.5% reduction in control homes.

The reasons for the lack of change in PM_{2.5} concentrations in the current study are unclear but may involve the disadvantages experienced by this group and include the dual barriers of a lack of opportunity to make changes and lack of support from other smoking adults. Qualitative interviews carried out with a selection of study participants [29] demonstrated that the intervention increased mothers' capability to change smoking behavior in the home, through better awareness of the risks to their children from SHS exposure. However, taking significant action was often constrained by their limited, and often changing, social and environmental opportunities, including smoking of other adults in the home setting. Recent work on the barriers, motivators and enablers to creating a smoke-free home have shown the complex interplay that exists in many homes can make the process difficult [30-31].

The intervention was based on review of behavioural interventions to reduce indoor smoking by parents which led to the development of the AFRESH behavior theory programme described in detail elsewhere [32]. Review of the literature indicated that incorporating objectively assessed feedback data and motivational interviewing appear to be the most popular adopted intervention methods and the most effective for SHS reduction with parents and caregivers of young children. Simply providing written information about the risks of SHS is not an effective strategy for this specific behaviour change type and instead ongoing support and interaction may play a vital role in the success of such SHS reduction interventions. The review also identified that it is necessary to strike a balance between making the intervention intensive enough to be effective but also ensuring too many sessions are not required, as the target population (often socioeconomically disadvantaged people) may find multiple session attendance problematic.

3.1. Strengths and limitations

In addition to the objective assessment of air-quality in each home, a particular strength of the study over other previous work was the duration of measurements. Air-quality data were collected for an average of 127 hours (5.3 days) during each stage in each home. In addition to the potential bias from the Hawthorne effect during short measurement periods [33], FSP workers reported that household activity (number of adults, number of cigarettes smoked, hours spent indoors etc.) was often highly variable due to complex issues around substance misuse, unemployment and changing relationships. There is significant potential to misclassify household concentrations of SHS through the use of

snapshot or even 24h measurement of $PM_{2.5}$ and longer duration measurement reduces the chance of people changing their behaviour whilst measurements are being made. Gathering data over 3-7 days is likely to have reduced these potential biases and provided a more accurate picture of SHS concentrations within each home at baseline and followup.

There were several limitations mostly due to the delivery challenges of real-world settings, structures and events. For example, a small number of participants moved home during the 6-months and so measurements were not always taken in the same setting. Similarly, partners or other adults living in the home sometimes changed between baseline and follow-up and so conditions were not always directly comparable. The intervention was delivered by 17 FSP workers and while all received identical training, the type of feedback and advice received by participants may have differed. The intervention was intentionally delivered as part of an existing relationship between the participant and their FSP worker, and possibly pre-existing differences in those relationships may have influenced the way the information was received and acted on.

In a few cases devices were switched off for periods of time during measurements. This was sometimes due to interruptions in electricity supply or may have been due to participants/others in the home deciding to switch the device off because of the desire to prevent the device measuring high levels of SHS during smoking. However, compliance was high with the number and duration of periods of lost data small in comparison to the time instruments were in homes. There was no evidence that data loss was more frequent

at follow-up than baseline and so we do not think this had a significant impact on our results.

A further limitation of the study is the use of PM_{2.5} as a marker for SHS. While this method has been used extensively in tobacco control research as a means of quantifying SHS concentrations[14-16], PM_{2.5} is not specific to tobacco smoke and can arise from non-smoking sources such as ambient air pollution, cooking and use of solid fuels. While it is possible that some increases of PM_{2.5} may have been due to non-smoking activity (particularly frying of food), it is also possible that smoking may have continued in these homes during periods when the participant was unaware of the behaviour of (other) smoking adults. We believe that our PM2.5 measurements are likely to provide robust information on household SHS data and note data from the Scottish Government ambient air quality monitor located in Hamilton, the administrative centre of the Lanarkshire area, that shows low PM concentrations and no discernible seasonal variation with monthly average PM_{10} concentrations across 2015 ranging from 14 to 21 μ g/m³ ($PM_{2.5}$ is typically about 60% the value of PM_{10} [34-35] and draw on $PM_{2.5}$ concentration data gathered from previous studies in Scotland that showed average concentrations in typical smokefree homes were 3 μ g/m³ [7] and 8-16 μ g/m³ even when combustion sources such as coal, wood and gas were used for heating or cooking purposes [36]. While measurement of air nicotine would provide a tobacco-specific method of quantifying SHS concentrations, this approach would currently not provide time-resolved information and would require expensive (and slow) chemical laboratory analysis: something that is likely to be a barrier to any future use of this intervention approach. New technologies under

development may provide real-time nicotine concentrations using low-cost methods [37] or utilise data on particle size distributions from different emission sources to differentiate SHS from other household aerosols [38]. Work on using the differential response of the Dylos to fine and coarse PM to identify SHS from other aerosols may also provide a way forward in quantifying the contribution of smoking to indoor air pollution [39].

The intervention method used delayed feedback of air quality data and provided this feedback only once at baseline and again at the one-month follow-up. It was necessary to take the device back to the office to perform the download and generation of the graphical and numerical feedback. This meant that feedback was typically provided one week after completion of the measurement period. There is evidence that rapid feedback is more effective in eliciting change in health and safety behaviors [40] and future work should examine methods to provide more immediate feedback to those engaging in smoke-free home interventions. Providing air quality feedback on just a single occasion (prior to the follow-up assessment) may be another reason that the study showed no effect on those receiving the intervention. Work by Klepeis and colleagues has begun to explore the use of warning lights and alarms on air quality monitors used to measure SHS [26]. Our group has also recently initiated a study to examine SHS concentration feedback using a Dylos connected to the internet to upload data in real-time to then provide participants with mobile phone SMS, email and telephone feedback and guidance [ClinicalTrials.gov Identifier: NCT03151421].

It is also possible that the intervention was not sufficiently strong to change behavior in a sustained manner. There is evidence from the literature on health warnings that 'shock' is often short-lived and does not produce long-term changes in smoking behavior [41]. This may be particularly true if there are significant barriers to enacting change and the subject has limited capacity to change: the single parent caring for a young child in a high-rise flat has fewer options in terms of modifying their smoking behavior compared to someone living with a partner in a ground floor home with access to garden space.

We also note that the current best practice of offering standard NHS advice on the health harms of SHS produced reductions in $PM_{2.5}$ concentration in the control arm of the study. We are not aware of any studies that have evaluated the effectiveness of 'standard' or 'very brief advice' on SHS from Health Professionals to smoking parents and recommend that future work looks at how this can be improved and better targeted to help protect children from SHS at home.

The FSP provides support to young mothers and the intervention was therefore targeted at this group despite the fact that other adults (partners, parents, visitors) may be smokers in the home. While the intervention hoped to provide mothers with the motivation and tools to engage with other adult smokers this is very likely to be subject to differences in family dynamics and social circumstances. Future work should consider an 'all household' approach where the intervention is delivered to all those who smoke in the home and have an interest in the child's health [42].

3.2. Conclusions

Personalised feedback of air-quality information using low-cost devices can be successfully integrated into routine services provided by health care providers. The overall results show that, in this group of disadvantaged mothers, there was no change in household SHS concentrations after delivery of the intervention. On this basis it seems unlikely that personalised air-quality feedback is sufficient, in itself, to change smoking behaviour in disadvantaged households in Scotland and similar countries where there is already a high awareness of the risks of SHS. Providing personalised air-quality feedback may not be suitable for all groups of smoking parents and may instead need to be tailored to those at a more advanced stage of change in terms of household smoking rules and, importantly, with the physical and social opportunities to change. Further work is required to identify the types of smoking households where air-quality feedback can play a role in supporting parents to protect their children from SHS. More immediate feedback methods delivered to all adults in the home may be key to achieving sustained household behavior change in relation to smoking.

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1479	SM and LA managed the FSP workers and the collection of the data; TH carried out the
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1481	production of the air-quality feedback for each participant. SS analysed the data, wrote
1482	
1483	the first draft of the manuscript and is the guarantor for this study. All authors made
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1485	contributions to and approved the final manuscript.
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