

Data linkage permissions protocols

Protocol for Phase 1 researcher data linkage visits to clubs in spring 2015

Resources

30 FFIT Follow Up Data Linkage Study Information Sheets

30 FFIT Follow up Data Linkage Consent Form Final

30 pens

Procedure

Aim to arrive around 30 minutes before session starts if possible. Check with the coach that it is OK for you to speak to the men before the programme starts.

As men arrive, introduce yourself and tell them you are a researcher from Glasgow University working with the team who developed and evaluated FFIT in 2011-12.

Tell them that although we know that FFIT works in the short and medium term, it is important to find out how it works in the long term too. One way we can do this in Scotland is to follow up participants through their health records.

Say that you are here tonight to ask if the men would be happy to give permission for the research team to link to their health data anonymously in future.

Give each man a copy of the Data Linkage Study Information sheet to read while they are waiting for the session to begin.

At the start of the session, recap the information you have already given the men, and hand out information sheets to any latecomers.

Ask the men if they have any questions.

Hand round the consent forms and pens, and ask all men to complete one. Make it clear that they can answer 'No' if they want.

Make yourself available to answer any questions privately as men complete their consent form.

Once the men have completed the forms, collect them (and the pens) and count to make sure you have one completed consent form for every man present.

End by thanking the men and coaches for their time, and wish the men good luck with their outcomes on FFIT.

Football Fans in Training



Data Linkage Feasibility Study

Coach Protocol for Phase 2a

in autumn 2015



Rationale

In 2011/12, Football Fans in Training (FFIT) was shown to be very effective in helping men improve their health risk by losing weight, becoming more active and eating a healthier diet, and keeping those changes going to 12 months.

These results from the randomized controlled trial of FFIT have been extremely important in securing ongoing funding for deliveries of FFIT in Scotland. However, this sort of ‘gold standard’ evidence is extremely expensive to collect.

In Scotland, we have a unique opportunity to use existing NHS health records to evaluate the effect of programmes like FFIT on people’s health. This is a great opportunity because:

- It is MUCH less expensive than a randomized controlled trial
- We can follow people up over the very long term – potentially for the rest of their lives.

Following the successful evaluation of FFIT, the programme has continued to be delivered through an increasing number of clubs within the SPFL. The SPFL Trust coordinate these ongoing deliveries, and routinely collect pre- and post- programme measurements as part of the ongoing audit of the programme.

The SPFL Trust is currently working with the FFIT research team at the University of Glasgow to test the feasibility of asking men taking part in ongoing deliveries of FFIT if they would give permission for us to access their medical records and follow up their health long term. This has the potential to allow us to follow several thousand men who have taken part in the FFIT programme to see if they continue to benefit from taking part over the long term.

If men give their permission (and if the research team gets funding to do this work), the SPFL Trust would provide their names, addresses and dates of birth to the FFIT research team at the University of Glasgow. The SPFL Trust may also provide the data collected by the coaches during the programme (e.g. pre- and post-programme weight and waist measures).

The FFIT research team would then securely pass information on names, addresses and dates of birth to the NHS Information Service Division that holds all Scottish health databases. The NHS Information Service Division would retrieve the men's health records from the databases, and make them completely anonymous, before making them available in a secure computer environment for analysis. Only authorised FFIT researchers would be able to look at this data, and their use of it would be closely monitored. They will only be able to look at patterns in health outcomes across all FFIT participants, and will never be able to identify any individual man.

If the feasibility study shows that enough men are happy to give permission for this 'data linkage' process, we will consider introducing the request as a normal part of the Week 2 delivery of FFIT.

What work has been done so far?

We have already asked men who have taken part in FFIT if they would give permission for data linkage to take place on two occasions:

- The first time was during the 12-month measurement sessions for the FFIT randomised control trial: 94% (648/688) of the men asked, said 'Yes'.
- Secondly, between January and April 2015, a member of the research team attended FFIT sessions at 18 clubs, to ask new recruits to the programme if they would give permission. This time 91% (269/296) said 'Yes'.

If the request for linkage to health records becomes a routine part of FFIT programme delivery, it is not feasible for this to be done by the research team. Instead, the coaches who are delivering FFIT will ask participants. It is this process that we are now testing.

Please follow this procedure at the start of Session 2

1) Welcome and accessing health records permissions 15min

Background A warm welcome for making it to Week 2 can be a great boost to the men's confidence and feeling of self-worth. People feel valued if you acknowledge their presence. If men are willing to give us permission to access their anonymised health records, this will help us get important evidence about how effective FFIT is over the long term.

Resources

- 1) Study information sheets for each man "Linking information about you from Football Fans in Training to your health records for long-term follow up"
- 2) Data linkage consent forms for each man "Permission for linking your data to your health records"
- 3) Sealable A4 envelope

Content, Style & Method of Delivery

- Try to welcome everyone by name as they arrive, give them the Study Information Sheet and Data Linkage Consent Form, and ask them to read these as they wait
- At the planned start time, welcome the group and take the register. Even if everyone has not arrived, start on time as a sign that you are following the time-keeping ground rule. If you start late, group members assume it's OK for them to arrive late
- Thank the men for completing all the paper work they have already done for the short term evaluation of FFIT, and say that the SPFL Trust and University of Glasgow are working together to find practical ways to measure the long term impact of the programme on men's health
- Say that one way of doing this is to ask men if they would be willing to give permission for the research team to gain access to their medical records to see how they get on health-wise in future years
- Explain the process will involve transferring their name, address, date of birth, and data collected during FFIT (e.g. weight, waist, number of sessions attended) to the research team at the University of Glasgow
- Explain that all information will be held securely at the University, with access to it restricted to a few named individuals
- Say that at the moment we are just investigating how many men would be happy to give permission, so that we can see if this is a viable strategy to follow the health of FFIT participants long term
- **HOWEVER**, if this approach does prove acceptable to most FFIT participants, giving their permission today means **we may link to their health records in future**
- Stress that their health records will be accessed within the NHS. Only authorised members of the research team will be given access to the anonymised data, and its use will be monitored
- **Stress that the research team will never be able to identify any individual man**
- Ask if there are any questions (use **DATA LINKAGE FAQS** to guide discussion)
- Ask all men to complete the permission form, and stress that it is entirely up to them whether they say 'yes' or 'no'; If they choose to say 'no' this will not affect their participation in FFIT in any way.
- Go round the men as they complete their permission form, to give them the opportunity to ask questions individually.

- Collect in completed permission forms and put them in the sealable A4 envelope provided
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AFTER THE SESSION:

- ❖ Please complete the **COVER SHEET** and place it in the envelope with the completed permission forms
- ❖ Lock the envelope away in a secure filing cabinet and liaise with the researcher at the University of Glasgow for collection by a secure courier service

DATA LINKAGE FAQS

1) Why are you asking me to give permission for my health records to be consulted?

The original FFIT study showed how taking part in FFIT improved men's weight and lifestyles right up to a year after first starting the programme. However, it is also important to find practical and affordable ways of finding out how men do over the longer term. Linking to participants' health records is a cost-effective way of doing this for all men taking part in FFIT who give us permission to do so.

2) How does the data transfer process work?

Information collected during the programme will be transferred to the FFIT research team at the University of Glasgow. The research team have to abide by very strict rules to protect personal data, and cannot themselves link individual men's names and addresses to their health records. Instead, they will send the information to the NHS Information Service Division who are allowed to extract the health records. Following very strict guidelines to protect confidentiality, the NHS Information Service Division completely anonymise the data and then send it back to the research team for analysis.

3) Who will actually extract information from my health records?

The linkage and information extraction from men's health records will be carried out by the electronic Data Research and Innovation Service (eDRIS), which is part of the NHS Information Service Division.

4) What data will be transferred?

The SPFL Trust will supply men's name, address and date of birth, and a few key items of information about them collected during the FFIT programme (e.g. number of sessions attended, and blood pressure, height, weight and waist measurements) to the FFIT research team at the University of Glasgow. The FFIT research team will then send names, addresses and dates of birth to the NHS Information Service Division that holds the health records. Staff in this division will extract relevant health information, anonymise it, and make the anonymised data available to the research team for analysis.

5) Will the researcher be given everything in my health records?

No. The research team will only be able to ask for health information that might be affected by men's participation in FFIT (e.g. hospital admissions, drug prescriptions, diabetes, cancers, death register).

6) Will the research team know what has happened to me health-wise?

No. The health record data will be completely anonymised before it is sent back to the research team. This means the research team will have no information that could be used to identify any individual man from his health records.

7) When will my health records be accessed?

The research team has no firm timeline for doing this. If the results of this feasibility study are positive (for example, if enough men give permission), then the research team would apply for additional funding to allow the linkage to take place and the health record information analysed.

8) Will I know when my health records are accessed?

No. We have no way of notifying you when your health records are accessed.

9) Why can't you bring the men back into the club?

It is extremely expensive to bring all men who have done FFIT back to the club to repeat measurements and assessments time and time again. Using health records will allow us to follow up many more men, over a longer period of time (potentially for the rest of their lives) for a fraction of the amount of money it would cost for repeated measurements. However, giving your permission for linkage to your health records (or deciding that you would rather not do this) will not affect your participation in anything the club might organise in relation to FFIT in the future.

10) Will there be a report of the results that we can see?

The results of this feasibility study will be written up into a report for the research project funder, the National Institute of Health Research, and this will be made available online (www.nihr.ac.uk). A non-academic report will also be compiled and this will be available on the FFIT website (www.ffit.org.uk). Both should be available sometime during 2016.

11) Should I use my NHS registered name (e.g. Roy vs Robert), my father/son has the same name?

Yes, please, don't worry if you have the same name as someone else in your family. The NHS will use your name and date of birth together to make sure they access the correct health records.

12) Can I think about this and get back to you?

Yes, it is quite alright for you to go away and think about it, and come back and tell us next week

COVER SHEET

- Please complete this cover sheet, and use the additional space to note any other questions not covered in the FAQs that the men ask you.
- Then return this cover sheet with the completed permissions to the research team

Name: _____

Club: _____

Date permissions collected: _____ FFIT Delivery Week: _____

Total no of men enrolled on FFIT: _____

Notes: