Managing cardiovascular risk for people with severe mental illnesses
The Primrose study manual for practice nurses and health care assistants

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www.ucl.ac.uk/primrose/about-us

We would also like to thank the Primrose Lived Experience Advisory Panel (LEAP), Dr Sheila Hardy and Vanessa Robinson for their feedback and input in to the development of the Primrose manual and training programme.

April 2017
Welcome to the Primrose study. This manual focuses on the service to be delivered to patients in the study. Please familiarise yourself with the manual. It will guide you through each stage of carrying out the Primrose service.

Overall responsibility for the Primrose study rests with Camden and Islington NHS Foundation Trust. The study is being coordinated by University College London and the Primary Care Research Network. The Chief Investigator is Dr David Osborn, Reader in Community Psychiatric Epidemiology at the Division of Psychiatry, University College London.

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Contents

1 About Primrose and this manual 3
   The Primrose Service Flow Chart 4
2 Organising and providing appointments 6
   First appointment flow chart 9
   Subsequent appointments flow chart 11
   The final appointment flow chart 13
3 Behaviour change strategy help sheets 14
   HELP SHEET 1: Setting a behavioural goal 15
   HELP SHEET 2: Involving supportive others 16
   HELP SHEET 3: Action planning 17
   HELP SHEET 4: Recording behaviour 18
   HELP SHEET 5: Reviewing progress 19
   HELP SHEET 6: Giving positive feedback 20
   HELP SHEET 7: Coping with setbacks 21
   HELP SHEET 8: forming habits 22
4 Primrose study procedures 23
5 Frequently asked questions (FAQs) 24
6 Definition of terms 25
7 List of appendices 26

APPENDIX 1: Primrose local resource directory template 27
APPENDIX 2: MY HEALTH PLAN 28
   My diary 29
APPENDIX 3: CVD health help sheets 30
   HELP SHEET 9: Lipids management 31
   HELP SHEET 10: Blood pressure management 32
   HELP SHEET 11: Impaired glucose 33
   HELP SHEET 12: Diabetes management 34
   HELP SHEET 13: Smoking 35
   HELP SHEET 14: Healthy eating 36
   HELP SHEET 15: Physical activity 37
   HELP SHEET 16: Drinking less alcohol 38
APPENDIX 4: Primrose appointment checklists 39
   First appointment checklist 40
   Appointments 2–13 checklist 41
   Final appointment checklist 42
APPENDIX 5: Primrose event notification form 43
1 About Primrose and this manual

1.1 | What is Primrose?
The Primrose study aims to evaluate a nurse-led service in primary care to reduce the risk of cardiovascular disease (CVD) in people with severe mental illnesses (SMI) including schizophrenia, bipolar disorder (manic depression), schizoaffective disorder or psychosis.

1.2 | Why is Primrose needed?
People with SMI often have very poor physical health. They are up to three times more likely to die from CVD. They have high rates of risk factors for heart disease and stroke including:

- Smoking
- High blood pressure
- Obesity and being overweight
- Abnormal lipids, with high total cholesterol and low HDL cholesterol
- Diabetes
- High fat low fibre diets
- Low levels of even moderate exercise

Reasons include:

- Poverty
- Lifestyle
- The stress of living with long term mental health problems
- Some medications, including antipsychotics, increase appetite and weight

This is why there is payment to GPs through the Quality Outcomes Framework (QoF) to provide physical health screening for patients on the SMI register.

There are reasons to be optimistic about helping people with SMI to be healthier:

- Many people with mental health problems attend their GP frequently
- They often want to give up smoking or reduce their weight
- Studies show that simple techniques can help them improve their physical health (for instance by quitting smoking).

1.3 | Who is Primrose for?
People aged 30-75 years of age with a diagnosis of SMI and CVD factors. These diagnoses will have already been made and the patient is likely to be on the Quality Outcomes Framework (QoF) SMI register. Those patients who have risk factors for CVD will already have been identified from the screening appointments. A researcher will have explained the study to them and will have obtained their consent to take part in the study. Patients will have raised total cholesterol (above 5.0 mmol/l) or a raised total cholesterol/HDL ratio (over 4) and have one or more of the following risk factors:

- High blood pressure (above 140mm Hg systolic and/or 90mm Hg diastolic)
- Body mass index over 30 kg/m2
- Current smoker
- Impaired glucose (HbA1c between 42-47 mmol/mol (6.0-.6.4%) and/or fasting plasma glucose between 5.5-6.9 mmol/l)
- A diagnosis of diabetes

1.4 | How the Primrose service will be provided
You will work with around 10 consenting patients with SMI in your practice to agree patient-led goals to improve their cardiovascular health. The aim of Primrose is that you will support the patient to lower their cholesterol, blood pressure or risk of developing diabetes by:

- Helping them to take statins, blood pressure or anti-diabetic medication
- Stop smoking
- Improve their diet
- Increase their physical activity
- Reduce their alcohol intake.

The goal may be different for each patient and will depend on their preference and on which CVD factors are most important to their health. Help sheets in this manual provide information on how to apply different skills to change these behaviours.

The Primrose Flow Chart on page 4 shows the risk factors to focus on and indicates an order of priority for addressing them. For example, if the patient has a poor diet and is prescribed a statin, the ideal goal would be to encourage them to take their medication properly before focusing on changing their diet.

For patients who are prescribed a new drug (e.g. statins), you will probably work with the GP. A key task is for you to encourage the patient to take their medication appropriately.
Choose one behavioural goal with each patient.

**Reducing Alcohol Intake**: Reduce alcohol intake.

**Lose Weight**: Lose weight.

**Stop Smoking**: Stop smoking.

**Manage Diabetes**: Manage diabetes.

**Manage Prediabetes**: Manage prediabetes.

**Lower Blood Pressure (BP)**: Lower blood pressure.

**Lower Cholesterol**: Lower cholesterol.

Start with the outcome furthest on the left relevant to the patient and their health. For example, if diabetes is not a primary concern, move on to smoking. When each goal is achieved, go to the next step and move down the flowchart. In some instances it may be possible to address more than one behaviour.
1.5 | Using this manual

This manual describes each stage of the Primrose service; from preparing for the first appointment to the end of the study.

You can go directly to the section for the relevant appointment. The appointment structures are arranged as follows:

- Preparing for the first appointment (page 7)
- The first appointment (pages 8-9)
- Preparing for subsequent appointments (page 10)
- Subsequent appointments – Appointments two-eleven (pages 10-11)
- Preparing for the final appointment (page 13)
- The final appointment (pages 13-14)

Table 1 | Primrose Resources

We have provided the following resources

<table>
<thead>
<tr>
<th>Resource</th>
<th>Purpose</th>
<th>Which appointment?</th>
<th>Where can I find it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Resource Directory</td>
<td>Record the names, contact details and referral requirements for specialist local health support services before the first appointment.</td>
<td>All</td>
<td>Page 7 and Page 27</td>
</tr>
<tr>
<td>Template</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Behaviour Change</td>
<td>Help Sheets for the skills which can help change behaviour. These include: Setting a Behavioural Goal, Involving Supportive Others, Action Planning, Recording Behaviour, Reviewing Progress, Giving Positive Feedback, Coping with Setbacks and Forming Habits.</td>
<td>All</td>
<td>Pages 14-22</td>
</tr>
<tr>
<td>Strategies Help Sheets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MY HEALTH PLAN</td>
<td>Record and review the patient's goals</td>
<td>All</td>
<td>Pages 28-29</td>
</tr>
<tr>
<td>CVD Health Help Sheets</td>
<td>Help Sheets include: Lipid Management, Blood Pressure Management, Impaired Glucose Tolerance Management, Diabetes Management, Stopping Smoking, Physical Activity, Healthy Eating and Drinking Less Alcohol</td>
<td>All</td>
<td>Pages 30-38</td>
</tr>
<tr>
<td>Appointment Checklists</td>
<td>To help you record what happens at each appointment.</td>
<td>All</td>
<td>Pages 40-42</td>
</tr>
<tr>
<td>Digital recorder</td>
<td>To record each appointment for training purposes</td>
<td>All</td>
<td>N/A</td>
</tr>
</tbody>
</table>

If you need extra copies of any of the resources listed above please contact the Primrose Study Manager at: a.burton@ucl.ac.uk. Alternatively the documents are available to download on the Primrose website: http://www.ucl.ac.uk/primrose/primrose-service
2 Organising and providing appointments

The Primrose study manual for practice nurses and health care assistants

The Primrose service consists of a minimum of 8 appointments and a maximum of 12 appointments with each patient over a 24-week period. Give yourself one hour to provide the first and final appointments and 20-30 minutes for every other appointment.

Check when they would prefer to see you. Some prefer afternoons; however this will be different for each individual.

- Please make sure you arrange the next appointment with the patient each time you see them. Record this in the patient’s MY HEALTH PLAN.
- There are two appointment schedules, depending on the type of support each patient wants:

### 2.1 | Suggested appointment schedule for patients referred to support services

If the patient would like help in attending diabetes services or would like to be referred to a support service e.g. stop smoking, improve diet, or others, please arrange to see the patient over a minimum of 8 appointments. Aim to arrange the first four appointments fortnightly and then decrease them to every four weeks depending on patient preference and progress.

**Flow chart 1 | Suggested appointment schedule for patients referred to support services**

<table>
<thead>
<tr>
<th>FIRST APPOINTMENT</th>
<th>Length: 1 hour</th>
<th>When? Week 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPOINTMENTS 2 – 4</td>
<td>Length: 20-30mins</td>
<td>When? Fortnightly</td>
</tr>
<tr>
<td>APPOINTMENTS 5 – 7</td>
<td>Length: 20-30mins</td>
<td>When? Monthly</td>
</tr>
<tr>
<td>FINAL APPOINTMENT</td>
<td>Length: 1 hour</td>
<td>When? Week 24</td>
</tr>
</tbody>
</table>

### 2.2 | Suggested appointment schedule for patients receiving support from you

If you are providing behavioural advice and support to the patient. (e.g. to take statins, blood pressure or anti-diabetes medication, stop smoking etc.) more intensive support may be needed. Aim for a maximum of 12 appointments with these patients. Aim to arrange the first four appointments weekly and then decrease them to every two-four weeks depending on patient preference and progress.

**Flow chart 2 | Suggested appointment schedule for patients receiving behavioural support from you**

<table>
<thead>
<tr>
<th>FIRST APPOINTMENT</th>
<th>Length: 1 hour</th>
<th>When? Week 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPOINTMENTS 2 – 4</td>
<td>Length: 20-30mins</td>
<td>When? Weekly</td>
</tr>
<tr>
<td>APPOINTMENTS 5 – 11</td>
<td>Length: 20-30mins</td>
<td>When? Every 2-4wks</td>
</tr>
<tr>
<td>FINAL APPOINTMENT</td>
<td>Length: 1 hour</td>
<td>When? Week 24</td>
</tr>
</tbody>
</table>
2.3 | Recording the appointments

A digital audio recorder is provided to record every Primrose appointment. Please check with the patient that they have consented to the appointments being recorded. Please reassure patients that this is for training purposes and that the recording will be anonymised.

Appointment checklists are also included in this manual (page 40-42) to help you record what happens at each appointment. Please print out and complete a checklist at each appointment.

The study team will telephone you after your first appointment to talk you through how to return the audio recordings to us through a secure data storage system.

2.4 | Preparing for the first appointment

Things to do before the first appointment:

Create a local resource directory. Some patients will need referral to your local specialist services. You can use the template on page 27 to create a ‘Primrose Local Resource Directory’. Include any services within your practice (e.g. smoking cessation, weight management) and external services such as:

- Specialist stop smoking services for SMI (in the community or mental health trusts);
- NHS stop smoking services;
- Physical activity or healthy eating programmes for SMI (in the community or mental health trusts);
- Specialist weight management services,
- Diabetes prevention services
- Local opportunities for support with weight reduction such as incentivised gym referrals, healthy living groups, dietician services;
- Local voluntary sector providers e.g. MIND.

Suggestions for updating the Primrose Local Resource Directory

- Consider contacting the Director of Nursing or a physical health lead at your local mental health trust regarding services for physical health for SMI.
- Check local authority and NHS websites;
- Check whether the information on the website appears to be up to date and that the services are still available.
- Try to update the Primrose Local Resource Directory every 3 months. It might help to set yourself a reminder.

1 | Practice staff roles: Decide who will be involved in the care of each patient and what their role will be i.e. you and which lead GP/s?

2 | Familiarise yourself with each patient’s physical and mental health.

Check in the medical records and with the patient’s GP for any treatment decisions made after their cardiovascular screening results (e.g. prescription of a statin or blood pressure medication, referral to a support service).

- It might help you to have more information about the patient’s mental health so that you can spot early signs of the patient becoming unwell. Read the medical records, discharge letters, letters from the psychiatrist and note whether there have been any recent hospital admissions.
- If you are concerned about anything in the patient’s medical records (e.g. abnormally high cholesterol, glucose or blood pressure, their mental health) speak to the patient’s GP.

3 | We suggest booking an hour for the first appointment with each patient.

4 | Please call the patient the day before the appointment to check that they can still attend. If not, please rearrange the appointment. Send a text reminder on the day of the appointment if your practice has the facility to do so.

5 | Before you see your first Primrose patient, please read through the manual again so that you know what to do before and during the first appointment.

6 | Ensure you have copies of the MY HEALTH PLAN (page 28-29).

7 | Any questions? If you have any questions or need more support before the first appointment, please phone or email the Primrose Study Manager on 020 7679 9031 or a.burton@ucl.ac.uk
2.5 | The first appointment

The first appointment aims to: 1 engage the patient; 2 set a patient-led goal to improve cardiovascular health (set a behavioural goal, make an action plan and record behavior); 3 use strategies to encourage the maintenance of the behaviour (give positive feedback and involve supportive others).

It might help to remind the patient that the Primrose service aims to help them improve their cardiovascular health such as taking a statin or blood pressure medication, stopping smoking, eating healthily, engaging in physical activity or drinking less alcohol.

The first appointment is summarised on the next page (page 9). This includes strategies to change behaviour and the corresponding help sheets (page 14-22).

CVD health help sheets to support you and the patient to change specific behaviours such as taking statins, blood pressure or anti-diabetic medication, stopping smoking, healthy eating, physical activity and drinking less alcohol can be found on page 30-38.

Engage the patient in a friendly and supportive way. You will already have these communication skills but some tips are listed below:

- **Providing general positive feedback** – Attending appointments, e.g. ‘it’s good to see you’, ‘well done on coming to this appointment’ to promote engagement with Primrose.
- **Active listening** – Repeat in a clear way what the patient says to you and check that you have understood them.
- **Ask open questions** – Ask questions that require more than a ‘yes’ or ‘no’ answer, for example, What are their health needs? What are they hoping to get out of the appointments?
- **Help the patient identify their own goals** – Don’t say ‘You should do this’. Just telling the patient that they should change can put people off. Ask how they think they could improve their health.
- **Give patients time to answer** – Some patients may take time to think about things – don’t be afraid of silences!
- **Use positive body language** – Use open and welcoming gestures and expressions, for example, smiling and looking at the client when they are talking. Avoid gestures that might be interpreted as defensive, aggressive or uninterested, for example, folding your arms or finger pointing.

Please remember to fill in the First Appointment Checklist (page 40) to help remind you to complete each step.
There are seven steps to work through with each patient at the first appointment:

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introduction</td>
</tr>
<tr>
<td></td>
<td>• Ask the patient if it’s OK to record the appointment. If yes – please switch on the recorder</td>
</tr>
<tr>
<td></td>
<td>• Explain the purpose of the Primrose service (See page 8)</td>
</tr>
<tr>
<td>2</td>
<td>Set a behavioural goal</td>
</tr>
<tr>
<td></td>
<td>• Ask the patient which area of their physical health they would like to focus on</td>
</tr>
<tr>
<td></td>
<td>• Together with the patient generate a list of possible behaviours and select one (e.g. taking their statin, antihypertensive or antidiabetic medication, stopping smoking, eating healthily, doing more physical activity, reducing drinking)</td>
</tr>
<tr>
<td></td>
<td>• Ensure that the goal is SMART</td>
</tr>
<tr>
<td></td>
<td>• Record the goal in the My goal section of MY HEALTH PLAN</td>
</tr>
<tr>
<td></td>
<td>• See HELP SHEET 1: Setting a behavioural goal</td>
</tr>
<tr>
<td>3</td>
<td>Involve supportive others</td>
</tr>
<tr>
<td></td>
<td>• Would the patient like to involve anyone else and in what way? (this could be one or more people, including their mental health worker, carer or friend) – See HELP SHEET 2: Involving supportive others</td>
</tr>
<tr>
<td></td>
<td>• Record how they would like them to be involved in MY HEALTH PLAN</td>
</tr>
<tr>
<td></td>
<td>• Record their contact details in the Primrose patient folder</td>
</tr>
<tr>
<td>4</td>
<td>Develop an action plan</td>
</tr>
<tr>
<td></td>
<td>• Together with the patient make an action plan as to when, where and with whom the target behaviour will be performed – See HELP SHEET 3: Action planning</td>
</tr>
<tr>
<td></td>
<td>• Record the action plan in the My action plan section of the MY HEALTH PLAN</td>
</tr>
<tr>
<td></td>
<td>• Encourage habit formation – See HELP SHEET 8: Forming habits</td>
</tr>
<tr>
<td>5</td>
<td>Encourage recording</td>
</tr>
<tr>
<td></td>
<td>• Together with the patient decide how progress towards the goal will be recorded – See HELP SHEET 4: Recording behaviour</td>
</tr>
<tr>
<td></td>
<td>• Encourage the patient to complete the My progress section of MY HEALTH PLAN</td>
</tr>
<tr>
<td>6</td>
<td>Arrange the next appointment</td>
</tr>
<tr>
<td></td>
<td>• Ask if they are happy with decisions made and if they have further questions</td>
</tr>
<tr>
<td></td>
<td>• Arrange the next appointment. Record the time and date on MY HEALTH PLAN. Allow 20-30 minutes for the next appointment</td>
</tr>
<tr>
<td>7</td>
<td>Take a copy of MY HEALTH PLAN</td>
</tr>
<tr>
<td></td>
<td>• Provide two copies of the MY HEALTH PLAN – one for the patient and one for the Primrose patient folder. Please also send a copy to the study team (<a href="mailto:a.burton@ucl.ac.uk">a.burton@ucl.ac.uk</a>)</td>
</tr>
</tbody>
</table>

SMART goals are:

- **Specific**: Clearly defined.
- **Measurable**: Such as measuring the number of minutes walked per day.
- **Attainable**: Set a realistic, attainable goal then work up to more ambitious goals.
- **Relevant**: Set a goal that is relevant to the patient so they can see the link between their behaviour and the health benefit.
- **Timely**: Set the goal within a time frame that works for the patient.
2.6 | Preparing for subsequent appointments – appointments 2-11

1 | If the patient would like to involve others in their care, contact them to explain the study and to agree their level of involvement based on patient preference and the person’s availability. Tell them the appointment date and time and discuss progress. Invite them to the appointment only if the patient has agreed (SEE HELP SHEET 2: Involving supportive others).

2 | If the patient has agreed for you to contact their mental health worker, ask if they are aware of any specialist physical health services available for patients with SMI – Add these to your Primrose Local Resource Directory (page 27).

3 | Telephone each patient the day before the appointment and remind them to bring their MY HEALTH PLAN. If they can’t attend, rearrange the appointment. Send a text reminder on the day of the appointment if your practice has this facility

4 | Please make sure you have the help sheets you will need.

2.7 | All subsequent appointments – appointments 2-11

All subsequent appointments are split into three sections: 1 engaging the patient; 2 using strategies to change behaviour to improve cardiovascular health (setting a behavioural goal, making an action plan and recording behaviour); 3 using strategies to maintain the change in behaviour (reviewing progress, involving others and coping with setbacks).

The process for carrying out subsequent appointments is summarised on page 11. This includes strategies that can help to change behaviour and the corresponding help sheets (page 14-22) which give you more information and guidance on using each strategy.

Behaviour help sheets to support you and the patient to change specific behaviours such as taking statins, blood pressure or anti-diabetic medication, stopping smoking, healthy eating, physical activity and drinking less alcohol can be found on page 30-38.

The aim of subsequent appointments is to review patient progress toward their goal and modify or set new goals as appropriate:

- Appointments should be face-to-face where ever possible. Only if you are having problems engaging the patient to attend appointments, please consider a telephone consultation depending on the specific goals agreed (e.g. if an agreed goal is that you will weigh the patient, they will need to attend the appointment).
- Please refer to page 6 for the schedule of all subsequent appointments
- Check the best time for each patient.
- Provide general positive feedback at each appointment, e.g. ‘it’s good to see you’, ‘well done on last week’, ‘well done for coming back’ to promote engagement with Primrose.
- Please remember to fill in the Subsequent Appointment Checklist (page 41) to help remind you to complete each step.
Subsequent appointments flow chart

There are eight steps to work through with each patient at subsequent appointments

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Record appointment</td>
</tr>
<tr>
<td></td>
<td>• If the patient has agreed to be recorded, please switch on the digital recorder!</td>
</tr>
<tr>
<td>2</td>
<td>Review progress</td>
</tr>
<tr>
<td></td>
<td>• Use MY HEALTH PLAN to review progress towards their goal – SEE HELP SHEET 5: Reviewing progress</td>
</tr>
<tr>
<td></td>
<td>• Give positive feedback on progress – SEE HELP SHEET 6: Giving positive feedback</td>
</tr>
<tr>
<td></td>
<td>• If the goal is achieved either set another or maintain the same goal</td>
</tr>
<tr>
<td></td>
<td>• If the goal is partly or not achieved, revise the action plan to reduce or set a new goal</td>
</tr>
<tr>
<td>3</td>
<td>Coping with setbacks</td>
</tr>
<tr>
<td></td>
<td>• Be positive about setbacks</td>
</tr>
<tr>
<td></td>
<td>• Tell the patient that change is rarely a smooth process and there are often setbacks along the way – SEE HELP SHEET 7: Coping with setbacks</td>
</tr>
<tr>
<td>4</td>
<td>Develop an action plan</td>
</tr>
<tr>
<td></td>
<td>• Together with the patient make an action plan as to when, where and with whom the target behaviour will be performed – SEE HELP SHEET 3: Action planning</td>
</tr>
<tr>
<td></td>
<td>• Record the action plan in the My action plan section of MY HEALTH PLAN</td>
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<td></td>
<td>• Encourage habit formation SEE HELP SHEET 8: Forming habits</td>
</tr>
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<td>5</td>
<td>Encourage recording</td>
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<tr>
<td></td>
<td>• Together with the patient decide how progress towards the goal will be recorded – SEE HELP SHEET 4: Recording behaviour</td>
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<td>• Encourage the patient to complete the My progress section of MY HEALTH PLAN</td>
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<td>6</td>
<td>Arrange the next appointment</td>
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<tr>
<td></td>
<td>• Ask if they are happy with decisions made and if they have further questions</td>
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<tr>
<td></td>
<td>• Arrange the next appointment. Record the time and date on MY HEALTH PLAN. Allow 20-30 minutes for the next appointment</td>
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<td>7</td>
<td>Take a copy of MY HEALTH PLAN</td>
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<td>• Provide two copies of MY HEALTH PLAN – one for the patient and one for the Primrose patient folder. Please also send a copy to the study team (<a href="mailto:a.burton@ucl.ac.uk">a.burton@ucl.ac.uk</a>)</td>
</tr>
<tr>
<td>8</td>
<td>Follow-up supportive others</td>
</tr>
<tr>
<td></td>
<td>• If the patient wanted their supportive other to attend but they were unable to, ask if you can phone them to discuss progress made and how the patient would like to be supported – SEE HELP SHEET 2: Involving supportive others</td>
</tr>
<tr>
<td></td>
<td>• Invite them to attend the next appointment if the patient requests this</td>
</tr>
</tbody>
</table>
2.8 | Preparing for the final appointment

Things to do before the final appointment:

1 | If the patient would like someone to attend the final appointment with them, contact this person to inform them of the date and time. Explain that this is the last appointment for Primrose. If they cannot attend, discuss how they can support the patient going forward.

2 | Telephone the patient the day before the appointment and remind them to bring their MY HEALTH PLAN. If they are unable to attend, rearrange the appointment. Send a text reminder on the day of the appointment if your practice has this facility.

2.9 | The final appointment

The aim of the final appointment is to review and praise achievements over the past 6 months and discuss how the patient can maintain behaviour change. The final appointment is split into two sections:

1 reviewing progress using strategies to change behaviour to improve cardiovascular health (Setting a behavioural goal, making an action plan and recording behaviour);

2 using strategies to maintain the change in behaviour (reviewing progress, involving others and coping with setbacks).

The process for carrying out the final appointment is summarised on page 13. This includes strategies that can help to change behaviour and the corresponding help sheets (page 14-22) which give you more information and guidance on using each strategy.

The final appointment should be face-to-face.

Please remember to fill in the Final Appointment Checklist (page 42) to help remind you to complete each step.
### The final appointment flow chart

There are seven steps to work through with each patient at the final appointment:

1. **Record appointment**
   - If the patient has agreed to be recorded, please switch on the digital recorder!

2. **Review progress**
   - Explain that this is the final appointment but that the researchers will contact them to complete questionnaires and clinical measures.
   - Use *MY HEALTH PLAN* to review progress towards their goal – SEE *HELP SHEET 5: Reviewing progress*.
   - Give positive feedback on progress – SEE *HELP SHEET 6: Giving positive feedback*.
   - If the goal is achieved either set another or maintain the same goal.
   - If the goal is partly or not achieved, revise the action plan to reduce or set a new goal.

3. **Coping with setbacks**
   - Be positive about setbacks.
   - Tell the patient that change is rarely a smooth process and there are often setbacks along the way – SEE *HELP SHEET 7: Coping with setbacks*.

4. **Maintaining an action plan**
   - Together with the patient make an action plan as to when, where and with whom the target behaviour will be performed – SEE *HELP SHEET 3: Action planning*.
   - Record the action plan in the *My action plan* section of *MY HEALTH PLAN*.
   - Encourage habit formation SEE *HELP SHEET 8: Forming habits*.

5. **Encourage recording**
   - Together with the patient decide how progress towards the goal will be recorded – SEE *HELP SHEET 4: Recording behaviour*.
   - Encourage the patient to complete the *My progress* section of *MY HEALTH PLAN*.

6. **Take a copy of MY HEALTH PLAN**
   - Ask if they are happy with decisions made and if they have further questions.
   - Provide extra copies of the *MY HEALTH PLAN* for the patient to use at home. Keep one copy for the Primrose patient folder. Please also send a copy to the study team ([a.burton@ucl.ac.uk](mailto:a.burton@ucl.ac.uk)).

7. **Follow-up supportive others**
   - If the patient wanted their supportive other to attend but they were unable to, ask if you can phone them to discuss progress made and how the patient would like to be supported – SEE *HELP SHEET 2: Involving supportive others*.
There are eight Help Sheets in this section which describe strategies that you can use at each appointment to help and encourage patients to improve their cardiovascular health. Specific Help Sheets (and when you might need to use them) are suggested within each appointment flowchart.

**3 Behaviour change strategy help sheets**

**The Help Sheets are:**

**HELP SHEET 1: Setting a behavioural goal**  
How to help the patient set their own goal

**HELP SHEET 2: Involving supportive others**  
Tips on who to involve and how to involve them

**HELP SHEET 3: Action planning**  
How to help the patient develop an action plan to achieve the goal

**HELP SHEET 4: Recording behaviour**  
How to use a diary to record behaviour

**HELP SHEET 5: Reviewing progress**  
How to review progress towards goals

**HELP SHEET 6: Giving positive feedback**  
How to encourage the patient using positive feedback

**HELP SHEET 7: Coping with setbacks**  
How to help the patient develop strategies to manage setbacks

**HELP SHEET 8: Forming habits**  
Tips on how to make behaviours become habit
HELP SHEET 1:
Setting a behavioural goal

Why set goals?
Goal setting helps to agree specific targets and gives the patient a greater sense of control over their health.

How to set a goal:

• Together with the patient, generate a list of possible behaviours and look at the pros and cons of each – getting the patient to actively consider the advantages to change can help when a patient is initially resistant to change.

• Help the patient choose a clinically relevant behaviour that also matters to them. Avoid choosing the behaviour yourself!

• Set one behaviour at a time rather than try to do too much, too soon.

• In general, goals are easier to achieve if they relate to a specific behaviour, such as taking medication every day or stopping smoking, rather than to the outcome of behaviour such as weight loss or reduction in blood pressure.

Set a “SMART” goal that is:

• **Specific**: State who, what, where, when, how often, with whom, in what context: e.g. ‘Steven will take his statin before he goes to bed every night’ rather than ‘take statin’.

• **Measurable**: Establish criteria so you and the patient know when the goal has been achieved. For instance go for a 30 minute walk three times a week. This is easier to measure than a vaguely specified goal like ‘walk more’.

• **Attainable**: Set a realistic, attainable goal. Make the first goal very easy for the patient to achieve to build the patient’s self-confidence.

• **Relevant**: Set a goal that is relevant to the patient.

• **Timely**: The goal should be set within a time frame that works for the patient.

• Record the agreed goal on the **MY HEALTH PLAN** and in the patient’s notes.

• The best way of changing behaviour and maintaining change is to build on small successes so start easy and gradually build up.
Why involve supportive others?

Patients may benefit from involvement of supportive others such as carers, family, friends, support workers and mental health workers in their care, who can help to encourage behaviour change. You should only involve supportive others in the patient’s care if the patient has agreed to this.

How to involve supportive others:

At the first appointment: Ask the patient if they would like to involve someone in their care. This could be their carer, mental health worker, friend and/or support worker. It could be more than one person.

• Explain that involving others may make it easier for them to achieve their goals.

• Discuss ways in which this person could be involved e.g.
  
  • Accompany them to appointments.

  • Remind them of their appointments.

  • Help them to take their medication.

  • Help them to monitor progress with their goal.

• Identify activities that could be done together to help them achieve their goal (e.g. exercise together/cook meals or go food shopping together).

• If they would like someone involved, ask if you can invite them to the appointments.

• If they do not want the person to come to the appointments, ask if you can contact the person to discuss how they can help.

• Document who will be involved and how in **MY HEALTH PLAN.**
An action plan states exactly where, when and with whom the target behaviour will be performed.

**Why form an action plan?**
Research shows that detailed action plans are helpful in achieving goals.

**How to form an action plan:**
Explain what an action plan is and that it will help the patient achieve his/her goal.

- As an example, if the goal set is ‘Steven will go for a 30 minute walk three days a week with his mental health worker John’ an action plan to achieve this goal might look like this.
  - **Where:** In the park.
  - **When:** On Monday, Thursday and Saturday after breakfast.
  - **With whom:** With John.
  - **For how long:** 30 minutes.

- Develop the action plan in collaboration with the patient.

- Record the agreed action plan on *MY HEALTH PLAN* and in the patient’s notes.
Why record behaviour?

• Once a goal and action plan have been set, it is important that the patient measures and records progress.

• People often underestimate or overestimate changes in their behaviour, e.g. underestimate the number of cigarettes smoked or overestimate the time they spend exercising. If people record their behaviour (self-monitor), they gain a realistic picture.

• Measuring behaviour can motivate patients when they see successes.

• Measuring behaviour can also identify any problems achieving goals.

How to record behaviour:

• Decide with the patient how the target behaviour might be measured.

• Record this unit of measurement (for example, number of minutes walked a day) next to ‘How I will check how I’m doing’ on MY HEALTH PLAN.

• Encourage the patient to complete the daily diary on MY HEALTH PLAN. Where the goal is to do something a few times a week rather than daily – they can indicate ‘non-behaviour days’ by putting an ‘X’.

For example, if the goal is physical activity, a way of measuring progress might be to record the number of minutes spent walking briskly each day.
HELP SHEET 5: 
Reviewing progress

Why review goals?
This is an opportunity to reflect on progress, identify any problems and generate solutions.

How to review progress:

• Use the My progress section on MY HEALTH PLAN to review the goal.

• Ask open questions that allow the patient to talk about their experience of trying to achieve their goal, e.g. ‘how did you get on last week?’ rather than ‘did you take your statin every day last week?’

• Praise the patient for any progress or effort made towards achieving the goal. You may have to probe to identify something to praise.

• If the patient has achieved their goal discuss either setting a new goal (see HELP SHEET 1: Setting a behavioural goal) or maintain the same goal.

• If the patient has partly achieved their goal (e.g. taking their statin 5 times a week, but not 7) or has made some progress towards their goal (e.g. reducing the number of biscuits eaten per day to 4 when the goal was 2) congratulate them on progress and identify lessons learnt.

Identifying factors influencing the patient’s behaviour:

• Help the patient to decide whether increasing capability, opportunity and/or motivation would help them achieve their goal. This can be done by asking ‘What could help you achieve what you want to achieve?’ and then explore by asking about these three components.

• ‘Would you be able to achieve your goal if you were more physically able to or if you had more information?’

• ‘Would you be able to achieve your goal if you had more opportunity or felt it was more acceptable to?’

• ‘Would you be able to achieve your goal if you wanted to do it more and didn’t want to do something else more?’

Generating solutions:

• Having identified barriers/facilitators, solutions can be generated, e.g. identify specific triggers that generate the urge (motivation) to eat unhealthy food and develop strategies to avoid these triggers.

• Translate the solution into a SMART goal and action plan (see HELP SHEET 1: Setting a behavioural goal and HELP SHEET 3: Action planning).

• If solutions to achieving this goal can’t be identified, either break it down into smaller steps that are easier to achieve, or consider setting a new more achievable goal (HELP SHEET 1: Setting a behavioural goal).
Why give positive feedback?
We all like positive feedback – it is motivating. It promotes engagement and encourages progress towards the patient’s goal.

How to give positive feedback:
Providing positive feedback on a goal:

- Feedback on the *behaviour* – draw attention to how many fewer calories they consumed based on their recording of the number of biscuits eaten than previously.

- Feedback on *effort* – praise the strategies they used to cut down on the number of biscuits eaten.

- Feedback on the *outcome* of the behaviour – weighing the patient and telling them how much weight they have lost or that they have not gained weight.
**HELP SHEET 7: Coping with setbacks**

**Why prepare for setbacks?**

Being prepared for setbacks before they happen helps the patient to get back on track after the setback. The two main aspects are identifying possible setbacks and to think about how they can avoid or manage situations which may cause setbacks.

**How to cope with setbacks:**

- Explain that setbacks often occur but that there are ways of getting back on track.

- Reassure the patient that change is rarely a smooth process with ups and down, but the key is to be moving in the right direction overall.

- Encourage the patient to see the setback as an opportunity to learn about the situations that are likely to lead to setbacks and what they can do to avoid setbacks in the future.

**Here are some strategies for coping with situations that could lead to a setback:**

- **Avoid** the situation.

- **Develop strategies** to manage risky situations.

  *For example, food shopping when hungry might encourage buying unhealthy food*

  *For example, if the patient says they smoked because they were stressed, develop a plan with the patient to do something else when they are next stressed, such as go for a walk or phone a friend.*
What is a habit?

- Habits are routines that become automatic as a result of doing them repeatedly at the same times and/or same places.

Why encourage patients to form a habit?

- Forming a habit can be an effective way of ensuring a behaviour is performed consistently without having to plan it. Examples might be taking a tablet at the same time and place every day or eating fruit with morning coffee.

- If a behaviour becomes a habit, it is more likely to happen.

How to encourage habit formation:

- To build a routine, link the action plan to activities that the patient does regularly. For example, if the patient takes their statin after they brush their teeth, over time the tooth brushing will become a cue to take their statin.

- Helping the patient to stick to routines will enable the routine to become a habit.

- Keeping diaries, arranging rewards and involving supportive others for sticking to routines are all helpful.
The following section describes the main research study procedures that you will need to be aware of. As well as seeing you at the Primrose service appointments, the patient will also have contact with a researcher who will collect data for the study over the course of one year.

If the patient no longer wants their Primrose service appointments we would still like them to attend the visits with the researcher (See section 4.1.3).

4.1 | Dealing with complaints and serious adverse events

4.1.1 | If the patient wants to make a complaint about the study

In the unlikely event that a patient wishes to make a complaint about any aspect of the study you should provide them with guidance as to how to do this. They should have options to contact someone other than you if they request this (e.g. the local PALS service):

- Manage the complaint in accordance with your practice’s complaints procedure
- Contact the Study Manager as soon as possible
- Complete an Event Notification Form (Page 43) and post/email this to the study manager as soon as possible.

It is our experience that complaints are rare from study patients. If a complaint does occur it can usually be dealt with most effectively if the study manager contacts the practice and patient as soon as possible to discuss the problem.

4.1.2 | If a patient experiences a serious adverse event or death

If a patient suffers a serious adverse event, by which we mean an unplanned hospital admission, or death during the course of this study please telephone the Study Manager. We will help you to complete an Event Notification Form (Page 43). Post/email this to the Study Manager as soon as possible.

4.1.3 | If a patient no longer wants to attend the Primrose service appointments

If a patient no longer wishes to attend the Primrose service appointments, find out the reasons why. Ensure that they understand that if possible, we would like them to attend the visits with the researcher, or at least the final follow up visit with the researcher, even if they no longer want to come to the Primrose service appointments. Emphasise that this does not mean they have to withdraw from the whole study. If they do want to withdraw from the study completely and the reason is due to a problem that can be resolved then attempt to find a resolution. If the patient is content with the resolution, they can remain in the study (even if they do not attend any further appointments with you). If a resolution is not agreed then:

- Thank the patient for their time and interest in the study. Explain that the information obtained to date will still be useful and that their withdrawal from the study will not affect their care at the practice in any way.
- Record on the Primrose Researcher Log that the patient has withdrawn from the study. Also record the date and the reason for withdrawal.
- Complete the Event Notification form (Page 43) and return to the Study Manager

4.2 | Additional support for you

Identify someone in the practice who you can go to with questions and concerns during the Primrose study. This could be a GP or nurse practitioner. You will have the support of the GP and others who are involved in the patient’s care when required (e.g. if a prescription is needed or if the patient becomes unwell).

Some patients may become unwell during the time they are taking part in Primrose. There should already be a plan in the patient’s mental health notes so that you know what to do in this situation. If there isn’t a plan, speak to the patient, their GP or psychiatrist/care worker to make one and include:

- Who should you call?
- Which services should you call?
- Where would they like to be taken if they become unwell?

If you have any other questions or concerns about the Primrose study please contact the Study Manager: Alex Burton. Tel: 020 7679 9031 Email: a.burton@ucl.ac.uk
5 Frequently asked questions (FAQs)

1 | What should I do if the patient wants to stop attending the appointments or attend less frequently?

Offer the patient a telephone follow-up if they are finding it difficult to attend face to face. Alternatively agree a different follow up time. Try not to extend the gap to more than one month between appointments. If the patient still does not want to attend see Section 4.1.3 if a patient no longer wants to attend the Primrose service appointments.

2 | What should I do if I’m concerned about the patient’s mental health?

See Section 4.2 Additional Support Available to You. Firstly talk to the patient. Discuss how the patient would like to deal with this and who you should contact. If you still have concerns, speak to the GP. If you are still concerned, contact the Primrose helpline on 020 7679 9031.

3 | What should I do if the patient has not shown up to their appointment?

Telephone the patient to find out why they didn’t attend. They may have forgotten or become unwell. Reassure them this is OK and offer another appointment. Tell the patient you will call or text (depending on which method the patient would prefer) to remind them.

4 | What should I do if I have tried to contact the patient but they are not available?

Leave a message with your name and contact details and ask the patient to call you back. Reassure them that everything is okay and that you are calling to rearrange the appointment. If the patient does not call back after a few days and they have identified a supportive other (e.g. carer, mental health worker, friend), contact this person and ask if they have any information or have had any recent communication with the patient.

5 | What should I do if the patient wants to stop taking their antipsychotic medication or try a different antipsychotic medication?

Explore the reasons why the patient wants to stop or change their medication. Advise them that you would like them to see their GP or psychiatrist to discuss their physical health and antipsychotic medication further.

6 | What should I do if the patient tells me they have stopped taking their antipsychotic medication?

Tell the patient that you need to talk to their GP or psychiatrist and that you would like them to see their GP or psychiatrist as soon as possible so that they can discuss the antipsychotic medication.

7 | What should I do if the patient isn’t motivated to change?

You may meet patients who do not want to make any changes. It may be that nobody has taken an interest in their physical health before or that they can’t see how to change. Emphasise that the patient is in control of making decisions, and that your role is to encourage them to explore their feelings and ideas around changing their behaviour. Ask the patient to think about the advantages of changing their behaviour. Refer to HELP SHEETS 1-8 for strategies on how to support patients who may not be motivated to change (e.g. if the patient finds it difficult to identify a goal refer to HELP SHEET 1: Setting a behavioural goal).

8 | What should I do if the patient isn’t progressing towards their goals?

Refer to HELP SHEET 5: Reviewing progress and HELP SHEET 7: Coping with setbacks for tips on how to explore and address this.
### Definition of terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-diabetic medication</td>
<td>Anti-diabetic drugs are medicines developed to stabilise and control blood glucose levels amongst people with diabetes. There are different types including:</td>
</tr>
<tr>
<td></td>
<td>• Insulin</td>
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<tr>
<td></td>
<td>• Pramlintide (Amylin)</td>
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<tr>
<td></td>
<td>• GLP-1 receptor agonists (such as Byetta and Victoza)</td>
</tr>
<tr>
<td></td>
<td>• Oral hypoglycemics (tablets)</td>
</tr>
<tr>
<td>Anti-hypertensive medication</td>
<td>Anti-hypertensive drugs treat hypertension (high blood pressure). The most important and most widely used are:</td>
</tr>
<tr>
<td></td>
<td>• ACE Inhibitors</td>
</tr>
<tr>
<td></td>
<td>• Calcium channel blockers</td>
</tr>
<tr>
<td></td>
<td>• Thiazide diuretics</td>
</tr>
<tr>
<td></td>
<td>• Angiotensin Receptor Blockers (ARBs)</td>
</tr>
<tr>
<td></td>
<td>• Beta blockers</td>
</tr>
<tr>
<td>Anti-psychotic medication</td>
<td>Antipsychotic medication is prescribed to control psychotic symptoms and prevent relapse. Older or “First Generation” medications are called typical antipsychotics while newer or “second generation” medications are called atypical. Both typical and atypical antipsychotics are effective at controlling positive symptoms of schizophrenia. Atypical medications seem to be more effective at controlling negative symptoms and may be helpful for treating mood symptoms of schizophrenia.</td>
</tr>
<tr>
<td>Bipolar Disorder</td>
<td>Formerly known as manic depression, this is a severe mood disorder (sometimes known as an affective disorder). It causes episodic shifts in a person’s mood which last for a few days to weeks. These episodes may be a high (mania) or low (depression) There are usually periods of normal mood in between.</td>
</tr>
<tr>
<td></td>
<td>• Symptoms of mania include: increased energy, elated mood, impulsive behaviour and enhanced self-esteem and belief in own powers.</td>
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<tr>
<td></td>
<td>• Symptoms of depression include: Low mood, poor sleep, lack of energy, feelings of worthlessness, low self-esteem and sometimes suicidal thoughts. Psychotic symptoms, such as paranoid beliefs or hearing voices can occasionally be experienced in bipolar disorder.</td>
</tr>
<tr>
<td></td>
<td>• It is thought that genetics, brain chemicals and environmental factors play a role in the illness. Mood stabilisers, antidepressants and antipsychotics are commonly prescribed to treat bipolar. Often a combination of medication can be useful. Psychological treatments also have a role to help people overcome depressive periods as well as understanding the illness and promoting self-care.</td>
</tr>
<tr>
<td>Cardiovascular Disease (CVD)</td>
<td>Includes all the diseases of the heart and circulation including coronary heart disease (angina and heart attack), failure, congenital heart disease and stroke. It is also known as heart and circulatory disease.</td>
</tr>
<tr>
<td>Impaired glucose tolerance</td>
<td>Impaired glucose tolerance refers to raised blood glucose beyond the normal range but it is yet high enough to diagnose diabetes; however the risk of developing diabetes and cardiovascular disease is raised. If impaired glucose tolerance is treated, it can help to prevent the development of diabetes and cardiovascular disease. The most effective treatment is lifestyle changes including eating a healthy balanced diet or doing regular physical activity.</td>
</tr>
<tr>
<td>Pre-diabetes</td>
<td></td>
</tr>
<tr>
<td>Psychosis</td>
<td>Psychosis is a medical term used to describe hallucinations (e.g. hearing or seeing things), or delusions (holding unusual beliefs that other people do not share). Common examples include hearing voices or believing that people are trying to do harm, delusions. Psychosis can be due to having a mental illness such as schizophrenia or bipolar disorder. It can also be caused by drug use, brain injury or extreme stress. People experiencing psychosis usually receive medication and talking therapy.</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>A mental illness that affects the way someone thinks. It affects about 1 in every 100 people.</td>
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<tr>
<td></td>
<td>• The symptoms of schizophrenia can be split into ‘positive’ and ‘negative’ symptoms.</td>
</tr>
<tr>
<td></td>
<td>• Positive symptoms include hearing or seeing things that are not real (hallucinations) and having unusual beliefs (delusions)</td>
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<tr>
<td></td>
<td>• Negative symptoms include lack of motivation and becoming withdrawn. These symptoms are generally more long-lasting and persistent.</td>
</tr>
<tr>
<td></td>
<td>• Schizophrenia is usually treated using antipsychotic medication and talking therapies.</td>
</tr>
<tr>
<td>Severe mental illness (SMI)</td>
<td>Refers to a group of mental illnesses which includes schizophrenia, bipolar disorder and other psychoses.</td>
</tr>
<tr>
<td>Statins</td>
<td>Statins are a group of medicines that can help lower rates of low-density lipoprotein (LDL) cholesterol (so called ‘bad cholesterol’) in the blood. They do this by reducing the production of LDL cholesterol inside the liver.</td>
</tr>
<tr>
<td>Total cholesterol/HDL ratio</td>
<td>Total cholesterol divided by HDL cholesterol reflects the fact that for any given total cholesterol level, the more HDL, the better. A total cholesterol/HDL ratio of 4 or less is generally regarded as desirable.</td>
</tr>
</tbody>
</table>
7 LIST OF APPENDICES
Before your first appointment in the Primrose study please use this template to list all local services and/or groups that you could refer patients to for support with **healthy eating, physical activity, stopping smoking and reducing drinking**. Ask other staff at your GP practice, search your NHS provider website and local council website and contact mental health workers to identify mental health specific services in your area.

<table>
<thead>
<tr>
<th>Name of service</th>
<th>Brief description of service</th>
<th>Who is the service for?</th>
<th>Referral method</th>
<th>Service address and email address</th>
<th>Telephone number</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight management services (diet and exercise)</td>
<td>e.g. Camden Sports &amp; Physical Service</td>
<td>e.g. Men and women aged 18+ with long term conditions including psychosis</td>
<td>e.g. GP referral</td>
<td>Sport and Physical Activity Section, Camden Town Hall, Argyle Street, London, WC1H 8EQ, <a href="mailto:sports@candi.gov.uk">sports@candi.gov.uk</a></td>
<td>020 7974 4090</td>
<td></td>
</tr>
</tbody>
</table>

Smoking services

Alcohol services

Diabetes prevention or diabetes management services

Other services
APPENDIX 2: MY HEALTH PLAN

My behavioural goal

My goal is to:

My action plan

<table>
<thead>
<tr>
<th>Where</th>
<th>I am going to do it:</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>I am going to do it:</td>
</tr>
<tr>
<td>How long</td>
<td>I am going to do it for (if relevant):</td>
</tr>
<tr>
<td>With whom</td>
<td>I am going to do it:</td>
</tr>
<tr>
<td>How</td>
<td>I will be supported by the people listed above:</td>
</tr>
</tbody>
</table>

My progress

How I will check how I'm doing (e.g. number of minutes spent doing physical activity):

My next appointment

Date
HOW I AM GETTING ON

There are two sections on each page where you can record your activity:

Option 1 Once a day
You can record activity once a day in the How I am getting on: Once a day section such as whether or not you took your statin that day. It might be helpful to write each day rather than trying to remember at the end of the week.

<table>
<thead>
<tr>
<th>WEEK NO</th>
<th>Mon</th>
<th>Tues</th>
<th>Weds</th>
<th>Thurs</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
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<tr>
<td></td>
<td>took statin</td>
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</tbody>
</table>

Option 2 Three times a day
If you would prefer, you can use the How I am getting on: Three times a day section to take a record of your activity three times a day. For example you may want to record what you eat and drink every day and how much e.g. two bags of crisps, one chicken sandwich. Or you may want to record how many cigarettes you smoke. It might be helpful to write each day rather than trying to remember at the end of the week.

<table>
<thead>
<tr>
<th>WEEK NO</th>
<th>Mon</th>
<th>Tues</th>
<th>Weds</th>
<th>Thurs</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
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<tr>
<td></td>
<td>AM 2 cigarettes</td>
<td>AM</td>
<td>AM</td>
<td>AM</td>
<td>AM</td>
<td>AM</td>
<td>AM</td>
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<tr>
<td></td>
<td>PM 1 cigarette</td>
<td>PM</td>
<td>PM</td>
<td>PM</td>
<td>PM</td>
<td>PM</td>
<td>PM</td>
</tr>
<tr>
<td></td>
<td>EVE 2 bags of crisps</td>
<td>EVE</td>
<td>EVE</td>
<td>EVE</td>
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<td>EVE</td>
<td>EVE</td>
</tr>
</tbody>
</table>

| 2       |     |      |      |       |     |     |     |
|         | AM 1 cigarette | AM | AM | AM | AM | AM | AM |
|         | PM | PM | PM | PM | PM | PM | PM |
|         | EVE | EVE | EVE | EVE | EVE | EVE | EVE |
APPENDIX 3:
CVD health help sheets
HELP SHEET 9: Lipids management

Cholesterol can be reduced by dietary change, physical activity and statins. Dietary change and physical activity should be considered before a statin unless the patient has a CVD risk score of 10% or more (check current NICE guidelines). If these patients have not already discussed or received a statin prescription, ask them if you can refer them to the GP to discuss this option.

Please refer to HELP SHEET 14: Healthy eating and HELP SHEET 15: Physical activity for further information on how to help patients change diet or increase physical activity.

Supporting the patient to take their statin

You may need to help patients monitor taking statins and any potential side effects. Some patients might be concerned about side effects (e.g. concerns that statins might have an impact on mental health). Make sure you give accurate information and monitor side effects e.g. myalgia, headaches, sleep disturbance, nausea. Discuss referring the patient back to their GP if side effects persist or worsen or if the patient develops pain, tenderness or weakness of muscles.

• If the patient is not taking their medication as prescribed, ask them why. The COM-B model (Capability – Opportunity – Motivation) described in HELP SHEET 5: Reviewing progress might help to understand whether they are not taking their medication because they can’t (capability or opportunity) or don’t want to (motivation).

• Explain that they are more likely to take their medication as prescribed if they get into the habit of taking it. The following strategies can help them to form a habit:

• Work with the patient to create ‘If-then’ rules. If-then rules work by creating a rule that IF the patient is in a particular situation, THEN they will perform a particular behaviour. For example “IF I have finished brushing my teeth in the evening, THEN I will take my tablet”. The situation becomes a trigger, or reminder, to perform the behaviour and through repetition the behaviour will become automatic and the habit is formed.

• Encourage the patient to get support from family and friends as positive encouragement is rewarding and can increase the frequency with which the behaviour is performed.

• Encourage the patient to record their statin use (see HELP SHEET 4: Recording behaviour and MY HEALTH PLAN) by recording when they have taken their medications.

Other Resources:

HELP SHEET 10: Blood pressure management

Blood pressure can be reduced by:

- Anti-hypertensive medication.
- Eating a healthy diet, particularly reducing salt intake and the excessive consumption of caffeine rich drinks such as coffee or coca cola.
- Regular physical activity.
- Stopping smoking.
- Reducing excessive drinking of alcohol.
- Please refer to Help Sheets 13-15 to help the patient to reduce their blood pressure.
- If blood pressure is higher than 140/90mmHg and they have not already discussed or received an antihypertensive prescription, ask them if you can refer them to the GP to discuss this option.

Aim for a target blood pressure below 140/90 mmHg. Offer to measure their blood pressure at each appointment to monitor their response. Record this in MY HEALTH PLAN.

Supporting the patient to take their antihypertensive

- If the patient is already prescribed an antihypertensive you should help them to monitor taking it as well as any side effects.
- Some patients might have side effects. Give accurate information about side effects and monitor for them. They could see the GP if the side effects persist.
- If the patient is not taking their medication properly, ask why. The COM-B model (Capability – Opportunity – Motivation) described in HELP SHEET 5: Reviewing progress might help to understand if they are not taking their medication because they can’t (capability or opportunity) or don’t want to (motivation).
- They are more likely to take their medication as prescribed if they get into the habit of taking it. The following strategies can help form habits:
  - Create ‘If-then’ rules. e.g. IF the patient is in a particular situation, THEN they will perform a particular behaviour. For example “IF I have finished brushing my teeth in the evening, THEN I will take my tablet”. The situation becomes a trigger, or reminder, to perform the behaviour.
  - Encourage the patient to get support from family and friends. Positive support and encouragement is rewarding and tends to increase the frequency with which the behaviour is performed.
  - Encourage the patient to record their antihypertensive use (see HELP SHEET 4: Recording behaviour and MY HEALTH PLAN) by recording when they have taken their medications.

Other Resources:

HELP SHEET 11: Impaired glucose

Discuss that their risk of developing diabetes can be reduced by:

- Eating a healthy diet, by increasing fibre intake and reducing the consumption of fat, particularly saturated fat.
- Increasing physical activity.

HELP SHEET 14: Healthy eating and HELP SHEET 15: Physical activity cover these.

If the patient is unable to or does not want to increase physical activity or improve diet:

- ask the patient if you can refer them to the GP to discuss a prescription (e.g. Metformin or Orlistat).

If the patient is prescribed medication you should help them monitor taking it and as well as any side effects:

- Some patients might have side effects. Give accurate information and monitor side effects for them. They could see the GP if the side effects persist.
- If the patient is not taking their medication properly, ask why. The COM-B model (Capability – Opportunity – Motivation) described in HELP SHEET 5: Reviewing progress might help to understand if they are not taking their medication because they can’t (capability or opportunity) or don’t want to (motivation).
- They are more likely to take their medication as prescribed if they get into the habit of taking it. The following strategies can help form habits:
  - Create ‘if-then’ rules. e.g. IF the patient is in a particular situation, THEN they will perform a particular behaviour. For example “IF I have finished brushing my teeth in the evening, THEN I will take my tablet”. The situation becomes a trigger, or reminder, to perform the behaviour.
  - Encourage the patient to get support from family and friends. Positive support and encouragement is rewarding and tends to increase the frequency with which the behaviour is performed.
  - Encourage the patient to record their medication use (see HELP SHEET 4: Recording behaviour and MY HEALTH PLAN) by recording when they have taken their medications.

Other Resources:

HELP SHEET 12: Diabetes management

If the patient has a diagnosis of diabetes when entered into the study they should already have a management plan in place. You may want to check the following:

- Have they been offered or received a patient education programme? If not, and if this programme is available, ask the patient if they would like to be referred to this.

- Do they attend a diabetes management clinic or service? Do they need any help in attending these services? If they do need help, suggest involving supportive others as a possible strategy (See HELP SHEET 2: Involving supportive others)

- Have they received lifestyle advice on physical activity and eating healthily? If they would like help with this please refer to HELP SHEET 14: Healthy eating and HELP SHEET 15: Physical activity for further information.

- Are they taking any medication? If so you may need to help them monitor taking it as well as monitoring any potential side effects.

Supporting the patient to take their medication

- Some patients might have side effects. Give accurate information about side effects and monitor for them. They could see the GP if the side effects persist.

- If the patient is not taking their medication properly, ask why. The COM-B model (Capability – Opportunity – Motivation) described in HELP SHEET 5: Reviewing progress might help to understand if they are not taking their medication because they can’t (capability or opportunity) or don’t want to (motivation).

- They are more likely to take their medication as prescribed if they get into the habit of taking it. The following strategies can help form habits:

  - Create ‘If-then’ rules. e.g. IF the patient is in a particular situation, THEN they will perform a particular behaviour. For example “IF I have finished brushing my teeth in the evening, THEN I will take my tablet”. The situation becomes a trigger, or reminder, to perform the behaviour.

  - Encourage the patient to get support from family and friends. Positive support and encouragement is rewarding and tends to increase the frequency with which the behaviour is performed.

  - Encourage the patient to record whichever goal you decide to work on (see HELP SHEET 4: Recording behaviour and MY HEALTH PLAN).

Other Resources:


- http://www.diabetes.org.uk/
HELP SHEET 13: Smoking

How to support patients to give up smoking:

• Everyone in the UK has access to free stop smoking services. These will provide behavioural support on a one-to-one basis or in a group plus medications.

• Tell patients they are four times more likely to stop smoking if they use if they use the NHS Stop Smoking Services than attempting to quit alone.

• Log on to http://www.ncsct.co.uk/publication_very-brief-advice.php for free online training to encourage patients to attend NHS Stop Smoking Services. The training should take no more than ten minutes and will train you to deliver a package of evidence-based behaviour change techniques, ‘Very Brief Advice’ that can be given in 30 seconds. It has three components – Ask, Advise and Act:

  • **ASK**: Assess current and past smoking behaviour, e.g. ‘Do you smoke?’ or ‘Are you still smoking?’

  • **ADVISE**: Provide information on consequences of smoking and smoking cessation, e.g. ‘the best way to stop is with specialist support and medication.’ Don’t ask if they want to stop.

  • **ACT**: Provide options for later/additional support such as referral to local NHS Stop Smoking Services and give advice on stop smoking medications such as nicotine replacement therapies and varenicline.

  • Patients might like to supplement attending NHS Stop Smoking Services with a mobile phone app. One that has been developed at UCL using evidence-based techniques is SF28 – a mobile phone app supporting people to prepare to quit smoking and through the first 28 days following their quit date. This can be downloaded for free from iTunes App Store.

Other resources:

• http://www.ncsct.co.uk/publication_very-brief-advice.php

• http://www.rcpsych.ac.uk/mentalhealthinfo/problems/smokingandmentalhealth.aspx

The Primrose study manual for practice nurses and health care assistants
HELP SHEET 14: Healthy eating

How to support patients to eat healthily:

If specialist services are available:

- Refer the patient to a dietician or specialist service offering support to eat healthily.

If specialist services are not available or if the patient does not want to be referred:

- Identify goals – Ask the patient to talk through the food and drink they have consumed over the last two days in order to identify any high calorie food and/or drink.

- Help the patient to set a goal to reduce or cut out one of the high calorie items and replace with a healthier item, e.g. swapping butter for low fat spread or sugary fizzy drinks for diet fizzy drinks (see HELP SHEET 1: Setting a behavioural goal).

- Start with a goal that is easy for the patient to achieve such as having a healthy snack instead of a high calorie snack once a day. This will build the patient’s self-confidence to set increasingly more ambitious goals.

- Tell the patient about positive examples of other patients and participants in studies of interventions to promote healthy lifestyles in people with severe mental illness (a technique known as social comparison). This may help them to develop more positive beliefs about their capabilities.

- Some patients report an increase in appetite soon after taking their antipsychotic medication and a corresponding belief that they are not capable of doing anything about this. Introduce the following techniques designed to change patients’ beliefs about their capabilities by saying “Other people who take antipsychotics have expressed the same concerns but have managed to deal with this using the following methods……I believe you can too”:
  
  - Suggest the patient has healthy food and drinks available to snack on rather than sugary snacks and drinks. If appropriate suggest the patient asks those they live with to support them by not keeping unhealthy or high calorie food and drinks in the house.
  
  - Suggest that the patient takes their antipsychotic medication when they go to bed so that the increase in appetite happens when they are asleep.
  
  - Suggest the patient talks to the GP or psychiatrist about other medication that might not have the same impact on their appetite.
  
  - Ask the patient to record their behaviour. For example, if the goal is to reduce the amount of cola drunk to one glass per day, ask the patient to keep a ‘drink diary’ recording what they had to drink and when. This will document any progress towards the goal or identify problems achieving the goal (see HELP SHEET 4: Recording behaviour and MY HEALTH PLAN).
  
  - If the patient wants to record their behaviour in more detail, encourage them to complete My diary where they can record more information about progress towards their goal.
  
  - Give the patient feedback on the outcome of their behaviour by weighing the patient during the appointment or encouraging the patient to weigh themselves once a week at home.

Other resources:

The following websites offer advice on healthy eating:

- http://www.weightconcern.org.uk/node/11
- http://www.nhs.uk/Tools/Pages/Toolslibrary.aspx
HELP SHEET 15: Physical activity

How to support patients to engage in physical activity:

If specialist services are available:

• Refer the patient to relevant specialist local services to promote physical activity.

If specialist services are not available or if the patient does not want to be referred:

• Help the patient to make the first goal set quite easy to build their self-confidence and encourage them to carry on with an achieved goal for a period of time before setting more ambitious goals. The overall target is for 150 minutes of moderate intensity activity (enough to make you slightly out of breath) per week to reduce the risk of CVD. However, if their current activity levels are low, this can be worked towards over time. You will have commonly heard advice for 5x 30 minute sessions per week but this can feel unachievable or unsustainable for many, and evidence suggests that the same effects can be gained by much shorter but more frequent activity (e.g. regular 5-10 minute brisk walks).

• A common problem patients report is feeling ‘sluggish’ or ‘lethargic’ because of antipsychotic medication and holding the belief that they don’t have the capability to engage in physical activity. Advise that physical activity gives you more energy, so it is important to do it even if feeling tired and that you can start with lower intensity/shorter periods and build up slowly as energy levels improve.

• Many people are put off by the thought of ‘exercise’, especially those who are sedentary for much of the time; and it is better to discuss increasing levels of physical activity more generally (including housework, gardening, walking etc.) that they could sustain longer term.

• Ask the patient to identify the benefits of physical activity. Tell them about positive examples of other patients and participants in studies of interventions to promote healthy lifestyles in people with severe mental illness (a technique known as social comparison). This may help them to develop more positive beliefs about their capabilities.

• When working with the patient to form an action plan, ask the patient about when the best time of day might be to plan to engage in physical activity. Encourage the patient to avoid setting a goal for a time when the sedative effects of their medication is at a maximum.

• Encourage the patient to record progress towards their goal (see HELP SHEET 4: Recording behaviour and MY HEALTH PLAN) by recording the number of minutes spent engaged in physical activity such as the minutes per day spent going for a walk.

• If the patient wants to record their behaviour in more detail, encourage them to complete My diary to record more information about progress towards their goal.

• Encourage the patient to use an aid such as a pedometer that will give them feedback on progress towards their goal.

Other resources:

The following websites offer advice on physical activity that is consistent with Department of Health advice:

• http://www.bhf.org.uk/heart-health/prevention/staying-active.aspx

• http://www.nhs.uk/Livewell/loseweight/Pages/10000stepschallenge.aspx

• http://www.nhs.uk/livewell/c25k/Pages/couch-to-5k.aspx
HELP SHEET 16: Drinking less alcohol

How to support patients to give up or reduce drinking:
If the patient has scored above 20 on the AUDIT screening tool and specialist services are available:

- Discuss referring the patient to a local alcohol support service.

If specialist services are not available or the patient has scored between 8 and 19 on the AUDIT screening tool or if the patient does not want to be referred to a specialist service:

- Provide brief advice for sensible drinking. The NHS recommends the Identification and Brief Advice for Sensible Drinking (SIPS) website. This includes training tools, screening tools and a patient leaflet containing information on the effects of alcohol on health, the number of units in alcoholic drinks and useful advice and contacts: http://www.alcohollearningcentre.org.uk/Topics/Browse/BriefAdvice/SIPS/BriefAdviceTrainingandTools/

- Encourage patients to set a goal to either reduce their units or stop drinking completely. Refer to the SIPS patient leaflet above which contains information on the number of units in alcoholic drinks. You can also increase the patient’s motivation to achieve these goals by:
  
  - Increasing intention to stop drinking by asking the patient to identify the benefits of stopping drinking. If they do not identify any benefits, provide ‘myth-busting’ information about the consequences of giving up, i.e. evidence that it improves sleep.
  
  - Ask the patient to identify practical strategies to reduce drinking. If they do not identify any strategies, suggest alternating soft drinks with alcoholic drinks when out with friends, changing to low-alcohol beer or reducing drink size (e.g. a half pint instead of a pint). Ask the patient to suggest alternative ways they could socialise or unwind that do not involve drinking.

  - Encourage the patient to record progress towards their goal (see HELP SHEET 4: Recording behaviour and MY HEALTH PLAN) by recording how many units they drink a week.

  - If the patient wants to record their behaviour in more detail, encourage them to complete My diary to record more information about progress towards their goal.

Other resources:
The following websites offer advice on alcohol reduction that is consistent with Department of Health advice.

- http://www.nhs.uk/Livewell/alcohol/Pages/Alcoholhome.aspx
- http://www.drinkaware.co.uk
APPENDIX 4: Primrose appointment checklists
**First appointment checklist**

For each activity enter one of the following: 2 = Done, 1 = Done to some extent, 0 = Judged appropriate to do but not done n/a = Judged not appropriate to do

<table>
<thead>
<tr>
<th>Practice ID:</th>
<th>Patient ID:</th>
<th>Date:</th>
<th>Summary</th>
<th>Appointment Activity</th>
<th>Enter 2, 1, 0 or n/a as described above</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td><strong>Before the first appointment</strong></td>
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<td>Primrose local resource directory compiled</td>
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<td>One hour appointment time booked</td>
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<td>Telephone reminder to patient to check they could still attend</td>
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<td>Rearranged appointment if patient could not attend</td>
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<td></td>
<td>Audio recorder switched on</td>
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<td></td>
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<td></td>
<td><strong>Introduction</strong></td>
<td>The purpose of the Primrose service was explained</td>
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<td></td>
<td>Facilitated the patient to identify an area of physical health to work on</td>
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<td></td>
<td><strong>Set a behavioural goal</strong></td>
<td>Facilitated the patient to generate a list of behaviours</td>
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<td></td>
<td>Facilitated the patient to set a patient-led behavioural goal using the SMART criteria: Specific, Measurable, Attainable, Relevant, Timely (An example of ‘Done to some extent’ – the behavioural goal met some but not all of the SMART criteria)</td>
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<td></td>
<td>The behavioural goal was recorded in <strong>MY HEALTH PLAN</strong></td>
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<td></td>
<td><strong>Involve supportive others</strong></td>
<td>The patient was asked if they would like to involve anyone in their care and how they would like them to be involved (An example of ‘Done to some extent’ – a ‘supportive other was identified but it was not agreed how they would be involved)</td>
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<td>How this person will be involved was written in <strong>MY HEALTH PLAN</strong></td>
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<td></td>
<td><strong>Develop an action plan</strong></td>
<td>Facilitated the patient to make an action plan including when, where and with who the behaviour would be performed (An example of ‘Done to some extent’ – the action plan specified some but not all of the following: where, when, how long and, if appropriate, with whom)</td>
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<td>The action plan was recorded in <strong>MY HEALTH PLAN</strong></td>
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<td></td>
<td><strong>Recording behaviour</strong></td>
<td>Facilitated the patient to decide how progress would be recorded</td>
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<td></td>
<td>How progress would be recorded was written in <strong>MY HEALTH PLAN</strong></td>
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<td><strong>Forming habits</strong></td>
<td>If appropriate, the patient was encouraged to form a habit by linking the action plan to activities that the patient does regularly (An example of ‘Done to some extent’ – the patient was encouraged to form a habit but not told how to do it)</td>
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<td></td>
<td><strong>Arrange next appointment</strong></td>
<td>The next 20-30 minute appointment was arranged</td>
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<td></td>
<td>**Take a copy of <strong>MY HEALTH PLAN</strong></td>
<td>The patient was given a copy of <strong>MY HEALTH PLAN</strong> to take away</td>
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<tr>
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<td></td>
<td>One copy of <strong>MY HEALTH PLAN</strong> was put in the Primrose study folder</td>
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<tr>
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<td></td>
<td><strong>Give positive feedback</strong></td>
<td>The patient was given positive feedback for attending the appointment</td>
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<td></td>
<td><strong>Email audio file</strong></td>
<td>Audio file and checklist sent to study coordinating centre. The patient identifier and appointment number is included in the filename.</td>
<td></td>
</tr>
</tbody>
</table>
This checklist is for appointments two – eleven. Please record the appointment number in the box above

For each activity enter one of the following: 2=Done, 1=Done to some extent, 0=Judged appropriate to do but not done n/a=Judged not appropriate to do

<table>
<thead>
<tr>
<th>Practice ID:</th>
<th>Patient ID:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary</td>
<td>Appointment Activity</td>
<td>Enter 2, 1, 0 or n/a as described above</td>
</tr>
</tbody>
</table>

**Before the appointment**
- Progress discussed with the patient’s supportive other (where applicable)
- Patient’s supportive other invited to the appointment (where applicable)
- 20-30 minute appointment time booked
- Telephone reminder to patient to check they could still attend
- Rearranged appointment if patient could not attend
- Audio recorder switched on

**Review progress**
- Facilitated review of progress towards the behavioural goal. *(An example of ‘Done to some extent’ – the patient was asked closed questions, ‘Did you do X?’ rather than open questions ‘How did you get on?’)*
- If appropriate, the COM-B model was used to identify factors influencing patient’s behaviour and solutions were generated. *(An example of ‘Done to some extent’ – the COM-B model was used to identify factors influencing the patient’s behaviour but solutions were not generated)*

**Coping with setbacks**
- If appropriate, patients were reassured that setbacks were part of the change process, they were encouraged to see them as a learning opportunity and given strategies for coping with situations that could lead to a setback. *(An example of ‘Done to some extent’ – the patient was reassured setbacks are part of the process and a learning opportunity but not given strategies for coping with situations that could lead to a setback)*

**Set a behavioural goal**
- If appropriate, facilitated the patient to generate a list of behaviours
- A patient-led behavioural goal was set using the SMART criteria: Specific, Measurable, Attainable, Relevant, Timely. *(An example of ‘Done to some extent’ – the behavioural goal met some but not all of the SMART criteria)*
- The behavioural goal was recorded in MY HEALTH PLAN

**Develop an action plan**
- Facilitated the patient to make an action plan including when, where and with who the behaviour would be performed. *(An example of ‘Done to some extent’ – the action plan specified some but not all of the following: where, when, how long, and, if appropriate, with whom)*
- The action plan was recorded in the MY HEALTH PLAN

**Recording behaviour**
- Facilitated the patient to decide how progress would be recorded
- How progress would be recorded was written in MY HEALTH PLAN

**Give positive feedback**
- The patient was given positive feedback for attending the appointment and for any attempts or progress towards achieving their goal. *(An example of ‘Done to some extent’ – some but not all opportunities to provide positive feedback were taken)*

**Forming habits**
- If appropriate, the patient was encouraged to form a habit by linking the action plan to activities that the patient does regularly. *(An example of ‘Done to some extent’ – the patient was encouraged to form a habit but not told how to do it)*

**Arrange next appointment**
- The next 20-30 minute appointment was arranged

**Take a copy of MY HEALTH PLAN**
- The patient was given a copy of MY HEALTH PLAN to take away
- One copy of MY HEALTH PLAN was put in the Primrose study folder

**Follow up supportive others**
- Supportive other(s) attended the appointment (if applicable)
- Supportive other(s) were contacted to discuss the appointment (if applicable)
- Supportive other(s) were invited to attend the next appointment (if applicable)
- The patient was asked if they would like to involve anyone in their care and how they would like them to be involved (if applicable). *(An example of ‘Done to some extent’ – a supportive other was identified but it was not agreed how they would be involved)*
- How this person will be involved was written in ‘My Health Plan’ (if applicable)

**Email audio file**
- Audio file checklist sent to study coordinating centre. The patient identifier and appointment number is included in the filename.
Final appointment checklist

For each activity enter one of the following: 2=Done, 1=Done to some extent, 0=Judged appropriate to do but not done n/a=Judged not appropriate to do

<table>
<thead>
<tr>
<th>Practice ID:</th>
<th>Patient ID:</th>
<th>Date:</th>
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<tbody>
<tr>
<td><strong>Before the appointment</strong></td>
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<tr>
<td>Progress discussed with the patient’s supportive other (where applicable)</td>
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<tr>
<td>Patient’s supportive other invited to the appointment (where applicable)</td>
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<td>20-30 minute appointment time booked</td>
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<td>Telephone reminder to patient to check they could still attend</td>
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<td>Rearranged appointment if patient could not attend</td>
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<td>Audio recorder switched on</td>
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<tr>
<td><strong>Review progress</strong></td>
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<tr>
<td>Facilitated review of progress towards the behavioural goal. (An example of ‘Done to some extent’ – the patient was asked closed questions, ‘Did you do X?’ rather than open questions ‘How did you get on?’)</td>
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<tr>
<td>If appropriate, the COM-B model was used to identify factors influencing patient’s behaviour and solutions were generated (An example of ‘Done to some extent’ – the COM-B model was used to identify factors influencing the patient’s behaviour but solutions were not generated)</td>
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<tr>
<td><strong>Coping with setbacks</strong></td>
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<tr>
<td>If appropriate, patients were reassured that setbacks were part of the change process, they were encouraged to see them as a learning opportunity and given strategies for coping with situations that could lead to a setback. (An example of ‘Done to some extent’ – the patient was reassured setbacks are part of the process and a learning opportunity but not given strategies for coping with situations that could lead to a setback)</td>
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<td><strong>Maintaining an action plan</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>An action plan was made including when, where and with who the behaviour would be performed (An example of ‘Done to some extent’ - the action plan specified some but not all of the following: where, when, how long and, if appropriate, with whom)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The action plan was recorded in the MY HEALTH PLAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Recording behaviour</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facilitated the patient to decide how progress would be recorded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How progress would be recorded was written in MY HEALTH PLAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Provide positive feedback</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient was given positive feedback for attending the appointment and for any attempts or progress towards achieving their goal (An example of ‘Done to some extent’ – some but not all opportunities to provide positive feedback were taken)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Forming habits</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If appropriate, the patient was encouraged to form a habit by linking the action plan to activities that the patient does regularly (An example of ‘Done to some extent’ – the patient was encouraged to form a habit but not told how to do it)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Take a copy of MY HEALTH PLAN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient was given extra copies of MY HEALTH PLAN to take away</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One copy of MY HEALTH PLAN was put in the Primrose study folder</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Follow up supportive others</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supportive other(s) attended the appointment (if applicable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supportive other(s) were contacted to discuss the appointment (if applicable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Email audio file</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audio file and checklist sent to study coordinating centre. The patient identifier and appointment number is included in the filename.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 5: Primrose event notification form

Notification of withdrawal, death, serious adverse event or complaint

<table>
<thead>
<tr>
<th>GP Practice Identifier:</th>
<th>Participant Identifier:</th>
<th>Date form filled in:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>DD / MM / YY</td>
</tr>
</tbody>
</table>

Completed by:

Telephone immediately with any notification of withdrawal, serious adverse event or complaint
Alex Burton (UCL) 020 7679 9031

(i) Patient request for withdrawal from study

<table>
<thead>
<tr>
<th>Date request received</th>
<th>DD / MM / YY</th>
</tr>
</thead>
<tbody>
<tr>
<td>What was the reason for the request?</td>
<td></td>
</tr>
<tr>
<td>Date Primrose Study informed</td>
<td>DD / MM / YY</td>
</tr>
<tr>
<td>Message taken by:</td>
<td>(at UCL)</td>
</tr>
</tbody>
</table>

(ii) Serious adverse event notification

<table>
<thead>
<tr>
<th>Date request received</th>
<th>DD / MM / YY</th>
</tr>
</thead>
<tbody>
<tr>
<td>What was the reason for the request?</td>
<td></td>
</tr>
<tr>
<td>Date Primrose Study informed</td>
<td>DD / MM / YY</td>
</tr>
<tr>
<td>Message taken by:</td>
<td>(at UCL)</td>
</tr>
</tbody>
</table>

CONTINUED…
## More details of serious adverse event (SAE)

<table>
<thead>
<tr>
<th>Date of event</th>
<th>DD / MM / YY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why was the event serious (choose most serious)</td>
<td>1 Resulted in Death</td>
</tr>
<tr>
<td></td>
<td>2 Life-threatening</td>
</tr>
<tr>
<td></td>
<td>3 Required inpatient hospitalisation or prolonged existing hospitalisation</td>
</tr>
<tr>
<td>Other medically important event, please specify:</td>
<td>6</td>
</tr>
</tbody>
</table>

| Where did the SAE take place? | 1 Hospital | 3 Home |
| | 2 Outpatient clinic/support service clinic | 4 GP practice |
| Other please specify: | 5 |

| Briefly describe SAE (include relevant symptoms, body site, and relevant tests/treatments received) | |

| SAE Status | 1 Resolved | 4 Worsening |
| | 2 Resolved with sequelae | 5 Fatal |
| | 3 Persisting | 6 Not accessible |

| Was this event expected in view of the patient’s clinical history? | 0 No | 1 Yes |
| Additional information | |

| Date Primrose Study informed | DD / MM / YY |
| Message taken by: (at UCL) | |
### (iii) Complaint notification

<table>
<thead>
<tr>
<th>Date of notification</th>
<th>DD / MM / YY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature of complaint</td>
<td></td>
</tr>
<tr>
<td>Date Primrose Study informed</td>
<td>DD / MM / YY</td>
</tr>
<tr>
<td>Message taken by:</td>
<td></td>
</tr>
<tr>
<td>(at UCL)</td>
<td></td>
</tr>
</tbody>
</table>

Send completed form to:

**Alex Burton**  
*Primrose Study Manager*  
UCL Division of Psychiatry  
6th Floor, Maple House  
149 Tottenham Court Road  
London, W1T 7NF  
[a.burton@ucl.ac.uk](mailto:a.burton@ucl.ac.uk)
Notes