7. ANNEXURES
DEPARTMENT OF PHARMACY PRACTICE
JSS COLLEGE OF PHARMACY ROCKLANDS, OOTY
(Off Campus, JSS University, Mysore)
(Established under section 3 of the UGC (Act))

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JSSCP/DPP/IRB/020/2009-10 Date 16.04.2010

To
Mr. Jayesh Kumar Bhatt, M. Pharm.,
Research Scholar,
TIFAC CORE,
JSS College of Pharmacy,
Ootacamund-643 001

Dear Mr. Jayesh Kumar Bhatt,

We have reviewed your below mentioned research proposal for the consideration for approval of the Institutional Review Board. After careful scrutiny of the same, I hereby inform you of the decision of the Board to sanction approval to carry out the said work.

TOPIC: Health Outcome measures and Vascular risk factors in patients with Type 2 Diabetes Mellitus receiving Vitamin C and Resveratrol supplementation.

Principal Investigator: Mr. Jayesh Kumar Bhatt

Kindly note that any changes in the proposed work should be brought to the notice of the Board and necessary approval should be obtained.

Thanking you,
Yours faithfully

(Dr. P.R. Anand Vijayakumar)
Member Secretary
Ref: CB48
CB/JB

30th September 2009

Mr Jayesh Kumar Bhatt
PhD Student
JSS College of Pharmacy
PO Box 20
"Rocklands"
Cotacamund 643001
The Nilgiris
Tamil Nadu
India

Dear Jayesh Kumar

Agreement for use of ADDQoL19 and DTSQs

Thank you for confirming the details needed to complete the agreement.

The agreement has now been finalised and four copies are enclosed. Please would you and Professor Nanjan sign and return two copies to my administrator Janet Bayfield; the others are for you each to keep. When Janet receives two signed copies back, she will send you a pdf copy of the questionnaires for photocopying for this study and the full user guidelines.

I would be very glad to receive copies of any manuscripts intended for publication or other reports arising from your work and seeing how the questionnaires perform. Please ensure if any reports/manuscripts contain the questionnaires that a 'for information only' copy is used.

If possible please send the manuscripts/reports electronically to Janet (janet.bayfield@rhul.ac.uk) who will pass them on to me.

With all good wishes

Yours sincerely

Clare Bradley PhD
Professor of Health Psychology

Encs
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Research Study: You are invited to participate in a research study of “Health outcome measures and vascular risk factors in patients with type 2 diabetes mellitus receiving vitamin C and resveratrol supplementation” being conducted by Mr. Jayesh Kumar Bhatt under the guidance of Dr. M. J. Nanjan, JSS College of Pharmacy, Post Box No. 20, Rockland’s, Ootacamund –The Nilgiris, Tamil Nadu, India.

Basis for Participant Selection: You have been selected to participate in the study because of your known diabetes condition that relates to the study inclusion criteria.

Purpose of Study: The main purpose of the study is to evaluate health outcome measures and vascular risk factor in the patient with type 2 diabetes mellitus by supplementing them with either vitamin C or resveratrol along with their antidiabetic drugs. This will be accomplished by regular follow up, intensive monitoring of the patients progress towards the desired therapeutic targets, assessment of humanistic outcome in diabetes mellitus and help them in the long term management of the disease.

Explanation of Procedures: Patients meeting the inclusion criteria are invited and enrolled in the study. Patient demographic data will be collected on a structured data collection form during base line visit. Information include patient ID, age, gender, education, weight, height, past medical and medication history, duration of disease, family history, current therapy, waste circumference, Body Mass Index (BMI), income, diet and exercise, blood pressure, smoking habit, etc.

Patient will be asked for fasting blood test during base line visit followed by three months and six month follow up visit, to evaluate various biochemical parameter include blood glucose, lipid profile, glycosylated haemoglobin and result will be discuss with patients.

Health Related Quality of Life assessment; patient knowledge and medication adherence behaviour will be assessed by using standardized questionnaires instruments. Patient interview and counselling will be done on every follow up visit. This study requires about 30min-1 hr of your time on every visit.

The study will be conducted at Government Head-quarters hospital Ootacamund, Nilgiris and Selected Private Hospitals.

Potential Risks and Discomforts: There is no potential risk and discomfort to the patient. There may be some emotional distress involved in discussing your diabetes. You may become tired of
talking or become bored with the subject matter.

**Potential Benefits:** This study will encourage the patients to understand their own disease, self management, and minimised the chronic complication associated with disease, ultimately lead to optimization of therapeutic outcome and health status.

**Assurance of Confidentiality:** Your identity will be protected to the extent allowed by the law. You will not personally be identified in any reports or publications that may result from this study. Data and records created by this project are owned by the University and the investigator team. You may view information collected from you by making a written request to the principal investigator. You may view only information collected from you, and not information collected about others participating in the project.

**Voluntary Participation and Withdrawal From the Study:** Your participation is voluntary and you may quit at any time. Your decision whether or not to participate will not affect your "treatment" or "present or future relationship with the JSS College of Pharmacy, Ooty or any other benefits to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time.

**Offer to Answer Questions:** You should feel free to ask questions now or at any time during the study. If you have any questions about this study, you can contact Mr. Jayesh Kumar Bhatt, Phone No. 09150296796, & email: jkbhatt@gmail.com.

**CONSENT STATEMENT**

By signing this form, you are stating that you have read and understand this form and the research project, and are freely agreeing to be a part of this study. If there are things you do not understand about the study, please ask the researchers before you sign the form.

<table>
<thead>
<tr>
<th>Participant’s Signature</th>
<th>Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Researcher obtaining consent:</th>
<th>Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
# PATIENT DEMOGRAPHIC DATA SHEET

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Patient Name:</strong> ..........................................</td>
<td><strong>3. Date of Birth:</strong> □ □/□ □/□ □ □ □ □ □ □ □</td>
</tr>
<tr>
<td><strong>2. Address:</strong> ..................................................</td>
<td><strong>4. Sex:</strong> Male □ Female □</td>
</tr>
<tr>
<td></td>
<td><strong>OR Age in Year:</strong> □ □</td>
</tr>
<tr>
<td><strong>5. Religion</strong></td>
<td>Hindu □ Muslim □ Christian □ Sikh □ Other ......................</td>
</tr>
<tr>
<td><strong>6. How much education have you had?</strong></td>
<td><strong>7. What is your marital status?</strong></td>
</tr>
<tr>
<td>Illiterate □ Primary □ Middle □ Secondary □ Higher Secondary □</td>
<td>Never married □ Married □ Separated/Divorced □ Widowed □</td>
</tr>
<tr>
<td>Graduate □ Post graduate □</td>
<td></td>
</tr>
<tr>
<td><strong>8. Where do you live most of the year?</strong></td>
<td><strong>9. How many people live with you?</strong></td>
</tr>
<tr>
<td>Your home □ Home of a relative □ Hostel/Paying guest/Rented □ Nursing home □ Other ____________</td>
<td>I live alone □ 1 person □ 2 people □ 3 people □ 4 people □ 5 or more □</td>
</tr>
<tr>
<td><strong>10. Which of the following best describes your current employment status?</strong></td>
<td><strong>11. Which of the categories best describes your total monthly combined household income from all sources?</strong></td>
</tr>
<tr>
<td>Working full-time, 48 hours or more a week □ Working part-time, less than 48 hours a week □</td>
<td>Less than 5,000 □ 5,000 to 9,999 □ 10,000 to 14,999 □ 15,000 to 19,999 □ 20,000 to 29,999 □</td>
</tr>
<tr>
<td>Unemployed or laid off and looking for work □ Unemployed and not looking for work □</td>
<td>30,000 to 39,999 □ 40,000 to 49,999 □ 50,000 to 59,999 □ 60,000 to 69,999 □ 70,000 and over □</td>
</tr>
<tr>
<td>Homemaker □ In school □ Retired □ Disabled, not able to work □</td>
<td>Something else? □ (Please specify): ________________________</td>
</tr>
</tbody>
</table>
### Medical History

**What year were you first told you had type 2 diabetes? (Please enter the year)** □□□□

<table>
<thead>
<tr>
<th>Current Medication for Diabetes with dose</th>
<th>Co-morbidity:.................................</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Medication:..................................</td>
</tr>
<tr>
<td>2.</td>
<td>1.</td>
</tr>
<tr>
<td>3.</td>
<td>2.</td>
</tr>
<tr>
<td>4.</td>
<td>3.</td>
</tr>
<tr>
<td>5.</td>
<td>4.</td>
</tr>
</tbody>
</table>

### Family History

<table>
<thead>
<tr>
<th>Diabetes</th>
<th>Yes □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type if know:</td>
<td></td>
</tr>
<tr>
<td>Type 1 Diabetes</td>
<td>□</td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
<td>□</td>
</tr>
</tbody>
</table>

**Which Family member at what age:**

Number of 1st degree relatives with diabetes (mother, father, brother or sister) □□

**Parent or sibling with diabetes** Yes □

**Does anyone in your family have Heart Disease?** Yes □ No □

*If yes, please enter details below*

<table>
<thead>
<tr>
<th>Problem</th>
<th>Age</th>
<th>Which family member</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Do you have any 1st degree relatives with diabetes (mother, father, brother or sister) who had/has

angina, stroke or a heart attack. Yes □ No □

### Smoking Status

<table>
<thead>
<tr>
<th>Non-smoker</th>
<th>Yes □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current smoker</td>
<td>Yes □</td>
</tr>
<tr>
<td>How many per day?</td>
<td>□□□□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ex-smoker</th>
<th>Yes □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date stopped smoking</td>
<td>□□/□□/□□□□</td>
</tr>
</tbody>
</table>

**How many used to smoke per day? □□□□**

### Social Habit

**Do you have alcoholic drink?** Yes □ No □ Ex-drinker □

**Date stopped Drinking □□/□□/□□□□**

**If yes; How many days in a week.**

1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □

**How many drink a day**

1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □
FOOD HABIT

Vegetarian □  Non-vegetarian □

How often do you eat fruit or vegetable? Everyday □  Not everyday □

EXERCISE

Do you have daily at least 30 minutes of physical activity at work or during leisure time?

Yes □  No □

PHYSICAL ASSESSMENT DATA SHEET

<table>
<thead>
<tr>
<th>S.NO.</th>
<th>PARAMETER</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Body Weight</td>
<td>.......kg</td>
</tr>
<tr>
<td>2.</td>
<td>Height</td>
<td>.........m</td>
</tr>
<tr>
<td>3.</td>
<td>Body Mass Index</td>
<td>.........kg/m^2</td>
</tr>
<tr>
<td>4.</td>
<td>Waist Circumference</td>
<td>.........cm</td>
</tr>
<tr>
<td>5.</td>
<td>Blood Pressure</td>
<td>.......... mmHg</td>
</tr>
</tbody>
</table>

Questionnaires Administration Status

<table>
<thead>
<tr>
<th>Questionnaires</th>
<th>Status (+/-)</th>
<th>Time Taken</th>
<th>Feed back</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Due Date for Visit V1:

Additional information:
ANNEXURE - V A

ADDQoL

This questionnaire asks about your quality of life – in other words how good or bad you feel your life to be.

Please put a "v" in the box that best indicates your response for each item.

What we would like to know is how you feel about your life now.

I) In general, my present quality of life is:

- [ ] excellent
- [ ] very good
- [ ] good
- [x] not too bad
- [ ] bad
- [ ] very bad
- [ ] extremely bad

Now we would like to know how your quality of life is affected by your diabetes, its management and any complications you may have.

II) If I did not have diabetes, my quality of life would be:

- [ ] very much better
- [ ] much better
- [ ] a little better
- [ ] the same
- [ ] worse

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ADDQoL © Prof Clare Bradley 24.2.04. Enquiries for S.Asians (India & UK) 7.11.04 (from asc UK English rev 13.11.04 (IAC))

Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK

Page 1 of 6
Please respond to the more specific questions on the following pages. For each aspect of life described:

For Part (a): put a "✓" in one box to show how diabetes affects this aspect of your life;
For Part (b): put a "✓" in one box to show how important this aspect of your life is to your quality of life.

1. (a) If I did not have diabetes, I would enjoy my leisure activities:
   - very much more
   - much more
   - a little more
   - the same
   - the same

(b) My leisure activities are:
   - very important
   - important
   - somewhat important
   - not at all important

2. Are you currently working, looking for work or would you like to work?
   Yes [ ] if yes, complete (a) and (b).
   No [ ] if no, go straight to Question 3.

(a) If I did not have diabetes, my working life would be:
   - very much better
   - much better
   - a little better
   - the same
   - worse

(b) For me, having a working life is:
   - very important
   - important
   - somewhat important
   - not at all important

3. (a) If I did not have diabetes, local or long distance journeys would be:
   - very much easier
   - much easier
   - a little easier
   - the same
   - more difficult

(b) For me, local or long distance journeys are:
   - very important
   - important
   - somewhat important
   - not at all important
4. Do you ever go on holiday or want to go on holiday?  
   Yes □ If yes, complete (a) and (b).  
   No □ If no, go straight to Question 6.

(a) If I did not have diabetes, my holidays would be:  
   □ very much better □ much better □ a little better □ the same □ worse

(b) For me, holidays are:  
   □ very important □ important □ somewhat important □ not at all important

5. If I did not have diabetes, physically I could do:  
   □ very much more □ much more □ a little more □ the same □ less

(b) For me, how much I can do physically is:  
   □ very important □ important □ somewhat important □ not at all important

6. Do you have family / relatives?  
   Yes □ If yes, complete (a) and (b).  
   No □ If no, go straight to Question 7.

(a) If I did not have diabetes, my family life would be:  
   □ very much better □ much better □ a little better □ the same □ worse

(b) My family life is:  
   □ very important □ important □ somewhat important □ not at all important

7. If I did not have diabetes, my friendships and social life would be:  
   □ very much better □ much better □ a little better □ the same □ worse

(b) My friendships and social life are:  
   □ very important □ important □ somewhat important □ not at all important
<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
</table>
| 8        | Do you have a close personal relationship (for example husband/wife, close family member, close friend) or would you like to have such a relationship?  
**Yes □** If yes, complete (a) and (b).  
**No □** If no, go straight to Question 9.  
(a) If I did **not** have diabetes, my closest personal relationship would be:  
very much better □  much better □  a little better □  the same □  worse □  
(b) For me, having a close personal relationship is:  
very important □  important □  somewhat important □  not at all important □  
| 9        | Do you have or would you like to have a sex life?  
**Yes □** If yes, complete (a) and (b).  
**No □** If no, go straight to Question 10.  
(a) If I did **not** have diabetes, my sex life would be:  
very much better □  much better □  a little better □  the same □  worse □  
(b) For me, having a sex life is:  
very important □  important □  somewhat important □  not at all important □  
| 10(a)    | If I did **not** have diabetes, my physical appearance would be:  
very much better □  much better □  a little better □  the same □  worse □  
(b) My physical appearance is:  
very important □  important □  somewhat important □  not at all important □  
| 11(a)    | If I did **not** have diabetes, my self-confidence would be:  
very much greater □  much greater □  a little greater □  the same □  less □  
(b) My self-confidence is:  
very important □  important □  somewhat important □  not at all important □  

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ADDOxL © Prof Clare Bradley: 24.2.04  English for R. Aslam (Kedma 8.1.03) 21.1.04 (from std. UK English rev. 13.10.03)

Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK
### Questionnaire Responses

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>12(a) If I did <strong>not</strong> have diabetes, my motivation would be:</td>
<td>very much greater</td>
</tr>
<tr>
<td>12(b) My motivation is:</td>
<td>very important</td>
</tr>
<tr>
<td>13(a) If I did <strong>not</strong> have diabetes, the way people in general react to me would be:</td>
<td>very much better</td>
</tr>
<tr>
<td>13(b) The way people in general react to me is:</td>
<td>very important</td>
</tr>
<tr>
<td>14(a) If I did <strong>not</strong> have diabetes, my feelings about the future (e.g. worries, hopes) would be:</td>
<td>very much better</td>
</tr>
<tr>
<td>14(b) My feelings about the future are:</td>
<td>very important</td>
</tr>
<tr>
<td>15(a) If I did <strong>not</strong> have diabetes, my financial situation would be:</td>
<td>very much better</td>
</tr>
<tr>
<td>15(b) My financial situation is:</td>
<td>very important</td>
</tr>
<tr>
<td>16(a) If I did <strong>not</strong> have diabetes, my living conditions would be:</td>
<td>very much better</td>
</tr>
<tr>
<td>16(b) My living conditions are:</td>
<td>very important</td>
</tr>
</tbody>
</table>
17 (a) If I did not have diabetes, I would have to depend on others when I do not want to:

- very much less
- much less
- a little less
- the same
- more

(b) For me, not having to depend on others is:

- very important
- important
- somewhat important
- not at all important

18 (a) If I did not have diabetes, my freedom to eat as I wish would be:

- very much greater
- much greater
- a little greater
- the same
- less

(b) My freedom to eat as I wish is:

- very important
- important
- somewhat important
- not at all important

19 (a) If I did not have diabetes, my freedom to drink as I wish (e.g. fruit juice, alcohol, sweetened hot and cold drinks) would be:

- very much greater
- much greater
- a little greater
- the same
- less

(b) My freedom to drink as I wish is:

- very important
- important
- somewhat important
- not at all important

If there are any other ways in which diabetes, its management and any complications affect your quality of life, please say what they are below:

Thank you for completing this questionnaire.
Diabetes Treatment Satisfaction Questionnaire: DTSQs

The following questions are concerned with the treatment for your diabetes (including insulin, tablets and/or diet) and your experience over the past few weeks. Please answer each question by circling a number on every scale.

1. How satisfied are you with your current treatment?
   very satisfied 6 5 4 3 2 1 0 very dissatisfied

2. How often have you felt that your blood sugar has been unacceptably high recently?
   most of the time 6 5 4 3 2 1 0 none of the time

3. How often have you felt that your blood sugar has been unacceptably low recently?
   most of the time 6 5 4 3 2 1 0 none of the time

4. How convenient have you been finding your treatment recently?
   very convenient 6 5 4 3 2 1 0 very inconvenient

5. How flexible have you been finding your treatment recently?
   very flexible 6 5 4 3 2 1 0 very inflexible

6. How satisfied are you with your understanding of your diabetes?
   very satisfied 6 5 4 3 2 1 0 very dissatisfied

7. Would you recommend this form of treatment to someone else with your kind of diabetes?
   Yes, I would definitely 6 5 4 3 2 1 0 No, I would definitely not recommend the treatment

8. How satisfied would you be to continue with your present form of treatment?
   very satisfied 6 5 4 3 2 1 0 very dissatisfied

Please make sure that you have circled one number on each of the scales.

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DTSQs © Prof Clare Bradley 1993. English for India 10.4.06 (from standard UK English rev. 7.094)
Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK.
ANNEXURE - VC

THE KNOWLEDGE, ATTITUDE, AND PRACTICE (KAP) QUESTIONNAIRE

1. Diabetes is a condition in which the body contains:
   - a higher level of sugar in the blood than normal
   - a lower level of sugar in the blood than normal
   - either a higher or a lower level of sugar in the blood than normal
   - I don’t know

2. The major cause of diabetes is:
   - an increased availability of insulin in the body
   - a decreased availability of insulin in the body
   - I don’t know

3. The symptom(s) of diabetes is/are:
   - increased frequency of urination
   - increased thirst and hunger
   - increased tiredness
   - slow healing of wounds
   - all the above
   - I don’t know

4. Diabetes, if not treated:
   - can lead to eye problems
   - can lead to kidney problems
   - can lead to foot ulcers
   - can lead to heart problems
   - all the above
   - I don’t know

5. The most accurate method of monitoring diabetes is:
   - checking blood glucose levels
   - checking urine sugar
   - I don’t know

6. In a diabetic patient, high blood pressure can increase or worsen:
   - the risk of heart attack
   - the risk of stroke
   - the risk of eye problems
   - the risk of kidney problems
   - all the above
   - I don’t know

7. A diabetic patient should measure his or her blood pressure:
   - once a year
   - once every six months
   - once every two months
   - once every month
   - need not check at all
   - I don’t know

8. When was your blood pressure checked last?
   - one week ago
   - one month ago
   - two months ago
9. The lifestyle modification(s) required for diabetic patients is/are:
   - weight reduction
   - stopping smoking
   - stopping alcohol intake
   - all the above
   - I don’t know

10. A diabetic patient should have his or her eyes checked:
    - once a year
    - once every six months
    - need not check at all

11. When did you have your last eye examination?
    - one month ago
    - six months ago
    - one year ago
    - two years ago
    - not done at all

12. Regular urine tests will help in knowing:
    - the status of liver function
    - the status of kidney function
    - the control of diabetes
    - I don’t know

13. When was your last urine exam?
    - one month ago
    - six months ago
    - one year ago
    - not done at all

14. The important factors that help in controlling blood sugar are:
    - a controlled and planned diet
    - regular exercise
    - medication
    - all the above
    - none

15. A regular exercise regimen will help in:
    - increasing blood circulation
    - enhancing insulin action
    - I don’t know

16. Do you exercise regularly?
    - Yes
    - No

17. Are you following a controlled and planned diet?
    - Yes
    - No

18. The well-balanced diet includes:
    - green leafy vegetables
    - fiber-rich food
19. For proper foot care, a diabetic patient:
   - should inspect and wash the feet daily
   - should select the best possible footwear
   - should walk barefoot inside and outside the house
   - should not walk barefoot inside and outside the house

20. Treatment of diabetes comprises:
   - antibiotic therapy
   - blood transfusions
   - substituting insulin
   - taking more bitter vegetables
   - I don’t know

21. Diabetes cannot be treated with:
   - insulin
   - glibenclamide
   - metformin
   - antibiotics
   - I don’t know

22. Upon control of diabetes, the medicines:
   - can be stopped immediately
   - can be stopped after one month
   - should be continued for life
   - I don’t know

23. Do you miss taking the doses of your diabetic medication?
   - Yes
   - No
   - If yes, how often?
   - occasionally
   - once a week
   - once a month

24. Are you aware of blood sugar levels falling below normal when you are taking drugs?
   - Yes
   - No
   - If yes, did you at any time experience any of the following symptoms?
     - weakness
     - confusion
     - visual disturbances
     - I don’t know

25. How do you manage hypoglycemic symptoms?
   - by taking sugar
   - by taking medicines
   - by taking insulin
   - I don’t know

Please make sure that you have tick one option on each of the scale.
Thank you for completing this questionnaire.
**BRIEF MEDICATION QUESTIONNAIRE (BMQ 2003)**

1. Please list below all medications you took in the **PAST WEEK**. For each medication you list, please answer each of the questions in the boxes below. [Use additional page if necessary]

<table>
<thead>
<tr>
<th>a. Medication name</th>
<th>b. How many days did you take it?</th>
<th>c. How many times per day did you take it?</th>
<th>d. How much did you take each time?</th>
<th>e. How many times did you miss taking it?</th>
<th>f. For what reason were you taking it?</th>
<th>g. How well does this medicine work for you? 1= very 2= somewhat 3= not at all 4= don’t know</th>
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</tr>
</tbody>
</table>

2. Do any of your medications bother you in any way? (Check one)  
   YES [ ]  NO [ ]  
   a. IF YES, please name the medication and explain how it bothers you.

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>In what way does it bother you?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

3. How much problem or concern are you having in the following areas [circle one]

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>a. My medication causes side effects.</td>
<td>None</td>
<td>A little</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>b. It is hard to remember all the doses.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>c. It is hard to pay for the medication.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>d. It is hard to open the container.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>e. It is hard to get my refill on time.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>f. It is hard to read the print on the container.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>g. The dosage times are inconvenient.</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>h. My medication causes other problem or concern.</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

If other problem or concern, please explain: ____________________________

4. Did you stop taking any medications in the **PAST SIX MONTHS**? (Check one)  
   YES [ ]  NO [ ]  
   If yes, please list the medications you stopped. For each, answer the questions in the boxes below.

<table>
<thead>
<tr>
<th>a. Medication name</th>
<th>b. For what reason were you taking it?</th>
<th>c. How well did the medicine work for you? 1= very 2= somewhat 3= not at all 4= don’t know</th>
<th>d. How much did it bother you? 0 = none 1= a little 2= a lot</th>
<th>e. For what reason did you stop taking it?</th>
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</table>

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NOTES:

1 The original instrument and validity study were published in: Svarstad BL, Chewning BA, Sleath BL, Claesson C. The brief medication questionnaire: A tool for screening patient adherence and barriers to adherence. Patient Education and Counseling. 1999;37:113-124. The current version (BMQ 2003) reflects some revision of items so they can be used with different dosage forms, a new item for assessing financial barriers (Q. 3c), a new item for assessing discontinued medications (Q. 4), and a procedure for calculating the total Adherence Risk Score (below).

2 The following procedures should be used for scoring the BMQ 2003. R= respondent

<table>
<thead>
<tr>
<th>Type of Screen</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Indication of nonadherence with current drug regimen (see Questions 1a-1e)</td>
<td></td>
</tr>
<tr>
<td>Did R fail to mention or list this prescribed drug without prompting?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R stop or interrupt therapy due to a late refill or other reason?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R report any missed days or missed doses for this drug?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R reduce or take less than prescribed amount per dose for any reason?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R take extra dose(s) or more medication than prescribed for any reason?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R report “don’t know” in response to Question 1a, 1b, 1c, 1d, or 1e?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R refuse to answer Question 1a, 1b, 1c, 1d, or 1e?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Subtotal A: Did R’s report indicate the presence of any nonadherence?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>B. Indication of negative beliefs or motivational barriers regarding efficacy, bothersome side effects, other concerns regarding a given drug and its effects (see Question 1g and 2-2a)</td>
<td></td>
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<tr>
<td>Did R report “not at all” or “don’t know” in response to Question 1g?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R name the prescribed drug as a drug that bothers him/her in 2a?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Subtotal B: Did R’s report indicate any of the above beliefs?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>C. Indication of recall barrier (see Question 1c and 3b)</td>
<td></td>
</tr>
<tr>
<td>Did R receive a multiple dose regimen (2 or more times/day)?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R report any difficulty remembering his/her medication?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Subtotal C: Did R’s report indicate the presence of any recall barriers?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>D. Indication of access barrier (see Question 3c and 3e)</td>
<td></td>
</tr>
<tr>
<td>Did R report any difficulty paying for medication?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Did R report any difficulty getting refills in time?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>Subtotal D: Did R’s report indicate the presence of any access barriers?</td>
<td>1=yes 0=no</td>
</tr>
<tr>
<td>E. Construction of Adherence Risk Scale (ARS) and other notes</td>
<td></td>
</tr>
</tbody>
</table>
| • If a summary scale is desired, the BMQ Adherence Risk Scale (ARS) is recommended. The ARS measures the number of adherence risk factors present and is constructed by adding the subtotals listed above (Subtotal A + Subtotal B + Subtotal C + Subtotal D= ARS). The ARS score ranges from 0 to 4, with “0” indicating no self-reported nonadherence or barriers to adherence and “4” indicating the presence of self-reported nonadherence and three types of barriers (belief or motivational barrier, recall barrier, and access barrier).
| • The Adherence Screen (Section A above) is designed to measure the presence or absence of self-reported nonadherence, not the extent of self-reported nonadherence. It is inappropriate to create a continuous variable by adding the seven items.
| • The four screens (A,B,C,D) are measured separately, because there are circumstances where the user may want to target patients with a certain type of nonadherence or barrier to adherence. For example, a positive recall screen (Subtotal C) predicts “sporadic nonadherence” that might be reduced by tailoring the patient’s dosage schedule, providing him/her with a medication organizer or memory aid, or encouraging the physician to simplify the regimen. |
Measures for Diabetes Mellitus: A Review

Jayesh Kumar Bhatt¹, Sabin Thomas², Nanjan M.J.¹*

Applied Research in Quality of Life

Accepted DOI: 10.1007/s11482-012-9168-8 (In Press).

Abstract

**Purpose:** To review selective health outcome measures for diabetes mellitus focussing on psychometric properties.

**Methods:** Systematic literature search was carried out to identify the instruments using electronic databases and manual search from relevant journals. Health outcome measures were assessed with predefined inclusion and exclusion criteria. Each instrument was assessed for patient related information, instrument content, reliability, validity and responsiveness to change.

**Results:** The electronic and manual search generated 317 relevant references. Twenty seven instruments that met the inclusion criteria were included in the study. Among the 27 instruments, 20 were in English language. Out of these, 14 instruments were developed in USA and the majority of the remaining in UK. The time taken to complete the questionnaires varied from 3-40 minutes. Appraisal of Diabetes Scale and Audit of Diabetes-Dependent Quality of Life are single index instruments and the remaining instruments have dimension in a range of three to nine. Appraisal of Diabetes Scale and Diabetes Treatment Satisfaction Questionnaire are the shortest questionnaire whereas Diabetes Care Profile is the longest. The Diabetes Treatment Satisfaction Questionnaire has more translations followed by Diabetes Medication Satisfaction, Audit of Diabetes-Dependent Quality of Life, Diabetes Health profile, Problem area in diabetes scale and Insulin Treatment Appraisal Scale. All the instruments were assessed for psychometric properties.

**Conclusions:** The Diabetes Care Profile, Diabetes-39, Diabetes Quality of life measure, Diabetes specific Quality of life scale, Diabetes Treatment Satisfaction Questionnaire, Diabetes symptom checklist-Revised and Diabetes Medication Satisfaction instruments have good psychometric properties and may be useful for the researcher interested in diabetes care. Most of the instruments were lacking in responsiveness evaluation and were developed and evaluated mainly in developed countries. There is a need, therefore, to focus future research on health outcome measures on the evaluation of responsiveness.
EFFECT OF ORAL SUPPLEMENTATION OF VITAMIN C ON GLYCEMIC CONTROL AND LIPID PROFILE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

International Journal of Pharmacy and Pharmaceutical Sciences

Manuscript No. 35-41/2011 (In Press)

Jayesh K Bhatt¹, Sabin Thomas², Nanjan MJ¹∗

ABSTRACT

Objective

Diabetes mellitus is one of the most common metabolic disorders which cause micro and macro vascular complications. The present study was designed to investigate the effect of vitamin C oral supplementation on glycaemic control and lipid profile in patients with type 2 diabetes mellitus.

Methods

Sixty two patients with type 2 diabetes mellitus were enrolled from Government Headquarters Hospital, Ootacamund, India, in a prospective, open label, randomized controlled trial. Patients were randomized into control and intervention groups. The control group received only oral hypoglycaemic agents whereas the intervention group received vitamin C (500 mg/day) oral supplementation along with oral hypoglycaemic agents for a period of 3 months. HbA₁C, fasting blood sugar, blood pressure, body weight, lipid profile, urea nitrogen, creatinine, total protein, ascorbic acid and oxidative stress were measured at the base line and at the end of 3 months by using specific methods.

Results

The results reveal that 3 months of vitamin C supplementation significantly improves the total cholesterol (mean ± SD 196.66±35.54 vs 178.16±26.61; p<0.05), LDL cholesterol (mean ± SD 113.67±27.64 vs 96.42±27.80; p<0.05) and urea nitrogen (mean ± SD 33±5.92 vs 29.71±7.27; p<0.05). Though not statistically significant, promising effects are also observed with respect to other variables.

Conclusion

Supplementation of vitamin C oral supplementation is found to be effective and has potential implications for the prevention of further complications in patients with diabetes mellitus.

Key words Diabetes Mellitus Type 2, Vitamin C, Glycaemic control, Lipid profile
Resveratrol Supplementation Improve Glycaemic Control in Type 2 Diabetes Mellitus:

A Prospective, Open Label, Randomized Controlled Study

Nutrition Research: Manuscript No. NR-11-410 (Under review)

Jayesh Kumar Bhatt1, Sabin Thomas2, Nanjan M.J.1*

Abstract

**Hypothesis** Oral resveratrol supplementation improves the glycaemic control in patients with type 2 diabetes mellitus. **Experiment design** Sixty two patients with type 2 diabetes mellitus were enrolled from Government Headquarters Hospital, Ootacamund, India, in a prospective, open label, randomized controlled trial. Patients were randomized into control and intervention groups. The control group received only oral hypoglycaemic agents whereas the intervention group received resveratrol (250 mg/day) along with their oral hypoglycaemic agents for a period of 3 months. HbA1c, lipid profile, urea nitrogen, creatinine and protein, were measured at the base line and at the end of 3 months by using specific methods. **Results** The results reveal that 3 months of resveratrol supplementation significantly improves mean HbA1c (mean ± SEM 9.99 ± 1.50 vs 9.65±1.54; \( p < 0.05 \)), systolic blood pressure (mean ± SEM 139.71±16.10 vs 127.92±15.37; \( p < 0.05 \)), total cholesterol (mean ± SEM4.70±0.90 vs 4.33±0.76; \( p < 0.05 \)) and total protein (mean ± SEM 75.6±4.6 vs 72.3±6.2; \( p < 0.05 \)) in type 2 diabetes mellitus. No significant changes in body weight, HDL and LDL cholesterol were observed. **Conclusion** Oral supplementation of resveratrol is found to be effective in improving glycaemic control and may provide a potential adjuvant for the treatment and management of diabetes.

**Keywords** Type 2 diabetes mellitus, Resveratrol, Metformin, Glibenclamide, Glycated haemoglobin, Lipid profile.