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The effect of the short term use of Zolpidem MR on poor sleep, daily pain and depression in arthritis patients

Benjamin, Daniela

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Appendix A

UNIVERSITY OF THE WITWATERSRAND

School of Physiology

CONSENT TO ACT AS A SUBJECT IN RESEARCH

I,_____ being 18 years or older,

consent to participating in a research project entitled: "Does the short term use of Zolpidem MR (Stilnox MR) improve both sleep and pain disorders in general practitioner patients?"

The procedures / questionnaires have been explained to me and I understand and appreciate their purpose, any risks involved, and the extent of my involvement. I have read and understand the attached information leaflet.

I understand that the procedures form part of a research project, and may not provide any direct benefit to me.

I understand that all experimental procedures have been sanctioned by the Committee for Research on Human Subjects, University of the Witwatersrand, Johannesburg.

I understand that my participation is voluntary, and that I am free to withdraw from the project at any time without prejudice.

_____ _____

Subject name and signature Date

_____ _____

Investigator name and signature Date

Appendix B

UNIVERSITY OF THE WITWATERSRAND

SCHOOL OF PHYSIOLOGY

General Health Questionnaire

Subject details

Date:.....

Subject name:.....

Subject code:.....(*Not to be completed by subject*)

Date of birth:.....

Age:.....

Height:.....

Weight:.....

Home tel:.....

Work tel:.....

Cell no:.....

E-mail:.....

1) Do you smoke? **YES / NO**

If yes, how much?.....

2) Do you drink alcohol? **YES / NO**

If yes, how much and what during the week?.....

How much and what during the weekend?.....

Eg. 2 glasses wine

General health

1) Are you aware that you are suffering from any of the following complaints?

Diabetes	**YES**	**NO**
Hypertension	**YES**	**NO**
Muscular disorders	**YES**	**NO**
Bone disorders	**YES**	**NO**
Joint disorders	**YES**	**NO**
Gastrointestinal disorders	**YES**	**NO**
Asthma	**YES**	**NO**
Epilepsy	**YES**	**NO**
Kidney disorders	**YES**	**NO**
Liver disorders	**YES**	**NO**
Autoimmune diseases	**YES**	**NO**
Sensory disorders	**YES**	**NO**
Anxiety or depression	**YES**	**NO**

Do you have any other health problems which have not been mentioned above? **YES / NO**

If yes, please specify.....

.....

.....

.....

.....

2) Are you currently on any regular medication (i.e. that you take at least once a day)? **YES / NO**

Name of medication:.....

Taken for what?.....

Since when?.....

3) Do you have a regular bedtime and wake up times? YES / NO

If yes; normal bedtime? ..... : .....

Normal wake-up time? ..... : .....

4) **<u>Pain</u>**

Do you currently have any medical conditions which cause pain? **YES / NO**

If yes: describe the pain and how often it occurs:.....

.....

.....

What treatment are you using for said pain?.....

Appendix C

McGill Pain Questionnaire

Subject:_____ Date:_____ Time:_____

PRI: S_____ A_____ E_____ M_____ PRI (TOTAL) _____ PPI_____
(1-10) (11-15) (16) (17-20) (1-20)

1
1. Flickering
2. Quivering
3. Pulsing
4. Throbbing
5. Beating
6. Pounding

2
1. Jumping
2. Flashing
3. Shooting

3
1. Pricking
2. Boring
3. Drilling
4. Stabbing
5. Lancinating

4
1. Sharp
2. Cutting
3. Lacerating

5
1. Pinching
2. Pressing
3. Gnawing
4. Cramping
5. Crushing

6
1. Tugging
2. Pulling
3. Wrenching

7
1. Hot
2. Burning
3. Scalding
4. Searing

8
1. Tingling
2. Itching
3. Smarting
4. Stinging

9
1. Dull
2. Sore
3. Hurting
4. Aching
5. Heavy

10
1. Tender
2. Taut
3. Rasping
4. Splitting

11
1. Tiring
2. Exhausting

12
1. Sickening
2. Suffocating

13
1. Fearful
2. Frightful
3. Terrifying

14
1. Punishing
2. Gruelling
3. Cruel
4. Vicious
5. Killing

15
1. Wretched
2. Blinding

16
1. Annoying
2. Troublesome
3. Miserable
4. Intense
5. Unbearable

17
1. Spreading
2. Radiating
3. Penetrating
4. Piercing

18
1. Tight
2. Numb
3. Drawing
4. Squeezing

19
1. Cool
2. Cold
3. Freezing

20
1. Nagging
2. Nauseating
3. Agonising
4. Dreadful
5. Torturing

The following 5 words represent pain in increasing intensity. Which word describes your present pain?

Mild Discomforting Distressing Horrible Excruciating

Present Pain Intensity (PPI)

What was your previous most painful experience? _____

_____

_____

People agree that the following 5 words represent pain in increasing intensity. They are:

1	2	3	4	5
Mild	Discomforting	Distressing	Horrible	Excruciating

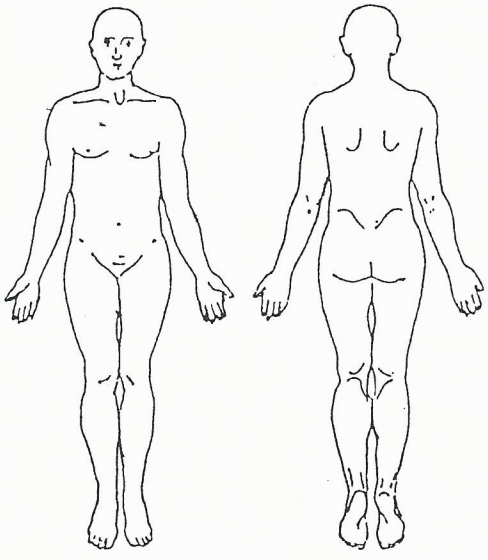
To answer the questions below, write the number of the most appropriate word in the space provided:

1. Which word describes the worst pain you have ever felt? _____
2. Which word describes the worst toothache you have ever had? _____
3. Which word describes the worst headache you have ever had? _____
4. Which word describes the worst stomach-ache you have ever had? _____
5. Which word best describes your present pain? _____

VAS pain rating

No pain ——————————————— The worst pain I have ever felt

Location of sensation



E = EXTERNAL
I = INTERNAL

Appendix D

PITTSBURGH SLEEP QUALITY INDEX (PSQI)

Name:..... ID No.:.....

Date:..... Age:.....

Instructions:
The following questions relate to your usual sleep habits during the past week *only*. Your answers should indicate the most accurate reply for the *majority* of days and nights in the past week. Please answer all questions.

1. During the past week, when have you usually gone to bed at night?

   USUAL BED TIME _____

2. During the past week, how long (in minutes) has it usually take you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past week, when have you usually gotten up in the morning?

   USUAL GETTING UP TIME _____

4. During the past week, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed).

   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer *all* questions.

5. During the past week, how often have you had trouble sleeping because you

   a) Cannot get to sleep within 30 minutes

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

   b) Wake up in the middle of the night or early morning

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

   c) Have to get up to use the bathroom

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

d) Cannot breathe comfortable

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

e) Cough or snore loudly

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

f) Feel too cold

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

g) Feel too hot

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

h) Had bad dreams

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

i) Have pain

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

j) Other reason(s), please describe:.....

.....

How often during the past week have you had trouble sleeping because of this?

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

6. During the past week, how would you rate your sleep quality overall?

Very good _____
Fairly good _____
Fairly bad _____
Very bad _____

7. During the past week, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

8: During the past week, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past week	Less than once a week	Once or twice a week	Three or more times a week .....

9. During the past week, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____
Only a very slight problem _____
Somewhat of a problem _____
A very big problem _____

10. Do you have a bed partner or roommate?

No bed partner or roommate _____
Partner/roommate in other room _____
Partner in same room, but not same bed _____
Partner in same bed _____

If you have a roommate or bed partner, ask him/her how often in the past month you have had ...

a) Loud snoring

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week .....

b) Long pauses between breaths while asleep

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week .....

c) Legs twitching or jerking while you sleep

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week .....

d) Episodes of disorientation or confusion during sleep

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week .....

e) Other restlessness while you sleep; please describe:.....

.....

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week .....

Appendix E

BECK INVENTORY

Name:..... Date:.....

On this questionnaire are groups of statements. Please read each group of statements carefully. Then pick out the one statement in each group which best describes the way you have been feeling the **PAST WEEK**, **INCLUDING TODAY**. Circle the number beside the statement you picked. If several statements in the group seem to apply equally well, circle each one. **Be sure to read all the statements in each group before making your choice.**

1. 0 I do not feel sad
   1 I feel sad
   2 I am sad all the time and I can't snap out of it
   3 I am so sad or unhappy I can't stand it

2. 0 I am not particularly discouraged about the future
   1 I feel discouraged about the future
   2 I feel I have nothing to look forward to
   3 I feel that the future is hopeless and that things cannot improve

3. 0 I do not feel like a failure
   1 I feel I have failed more than the average person
   2 As I look back on my life, all I can see is a lot of failures
   3 I feel I am a complete failure as a person

4. 0 I get as much satisfaction out of things as I used to
   1 I don't enjoy things the way I used to
   2 I don't get real satisfaction out of anything anymore
   3 I am dissatisfied or bored with everything

5. 0 I don't feel particularly guilty
   1 I feel guilty a good part of the time
   2 I feel quite guilty most of the time
   3 I feel guilty all of the time

6. 0 I don't feel I am being punished
   1 I feel I may be punished
   2 I expect to be punished
   3 I feel I am being punished

7.
0 I don't feel disappointed in myself
1 I am disappointed in myself
2 I am disgusted with myself
3 I hate myself

8.
0 I don't feel I am any worse than anybody else
1 I am critical of myself for my weakness or mistakes
2 I blame myself all the time for my faults
3 I blame myself for everything bad that happens

9.
0 I don't have any thoughts of killing myself
1 I have thoughts of killing myself, but I would not carry them out
2 I would like to kill myself
3 I would kill myself if I had the chance

10.
0 I don't cry anymore than usual
1 I cry more now than I used to
2 I cry all the time now
3 I used to be able to cry, but now I can't even though I want to

11.
0 I am no more irritated now than I ever am
1 I get annoyed or irritated more easily than I used to
2 I feel irritated all the time now
3 I don't get irritated at all by the things that used to irritate me

12.
0 I have not lost interest in other people
1 I am less interested in other people than I used to be
2 I have lost most of my interest in other people
3 I have lost all of my interest in other people

13.
0 I make decisions about as well as I ever could
1 I put off making decisions more than I used to
2 I have greater difficulty in making decisions than before
3 I can't make decisions at all anymore

14.
0 I don't feel I look any worse than I used to
1 I am worried that I am looking old or unattractive
2 I feel that there are permanent changes in my appearance that make me look unattractive
3 I believe that I look ugly

15.
0 I can work about as well as before
1 It takes an extra effort to get started at doing something
2 I have to push myself very hard to do anything
3 I can't do any work at all

16.
0 I can sleep as well as usual
1 I don't sleep as well as I used to
2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep
3 I wake up several hours earlier than I used to and cannot get back to sleep

17.
0 I don't get more tired than usual
1 I get tired more easily than I used to
2 I get tired from doing almost nothing
3 I am too tired to do anything

18.
0 My appetite is no worse than usual
1 My appetite is not as good as it used to be
2 My appetite is much worse now
3 I have no appetite at all anymore

19.
0 I haven't lost much weight, if any lately
1 I have lost more than 5 pounds
2 I have lost more than 10 pounds
3 I have lost more than 15 pounds

I am purposely trying to lose weight by eating less? Yes / No

20.
0 I am no more worried about my health than usual
1 I am worried about physical problems such as aches and pains, or upset stomach, or constipation
2 I am very worried about physical problems and it's hard to think of much else
3 I am so worried about my physical problems, that I cannot think about anything else

21.
0 I have not noticed any recent change in my interest in sex
1 I am less interested in sex than I used to be
2 I am much less interested in sex now
3 I have lost interest in sex completely

M001 MQ1

PA SCORE:

PHYSICAL ACTIVITY QUESTIONNAIRE

Appendix F

points for the week = (29,1)

1. SPORTING ACTIVITIES/EXERCISE DURING THE PAST WEEK

mins for week total = 3940
level 1 = 1900
level 2 = 1740
level 3 = 300

1.1 Did you go to gym or a sports club during the week (**MONDAY TO FRIDAY**)?

(Yes=1)	No=0

1.2 If Yes please complete the following table with:
How often you went to gym or go to your sports club? What type of exercise you did in the gym or at the sports club? How long did you spend doing each exercise?

Type of exercise e.g. running, spinning weights, yoga, pilates etc.	Times per week					Minutes/ Time	Intensity				
	Mon	Tue	Wed	Thur	Fri		V. low	Low	Med	High	V. high
RUNNING (6.0)	✓		✓		✓	1 HOUR			✓		

1hr × 3 = 180 mins / week for running @ level 3

2. SPORTING ACTIVITIES/EXERCISE DURING THE PAST WEEKEND

2.1 Did you go to gym or a sports club during the weekend (**SATURDAY AND SUNDAY**)?

Yes=1	(No=0)

2.2 If Yes please complete the following table with:
How often you went to gym during the weekend? What type of exercise you did in the gym or at the sports club? How long did you spend doing each exercise?

Type of exercise e.g. running, spinning, weights, yoga, pilates etc.	Times per weekend		Minutes/Time	Intensity				
	Sat	Sun		V. low	Low	Med	High	V. high

2.3 Did you take part in any sporting events on the weekend e.g. cycle race, running race, hiking event etc?

Yes=1	(No=0)

2.4 If Yes please complete the table with the following:
What type of sporting events did you take part in? How long did they last?

Type of event e.g. running, cycling, hiking, walking etc.	Times per weekend		Minutes/Time	Intensity				
	Sat	Sun		V. low	Low	Med	High	V. high

3. INFORMAL ACTIVITIES

Did you engage in any physical activity during the day (weekdays and weekend) but **NOT** at a sports club e.g. cleaning, cooking, ironing, moving furniture, gardening, walking the dog etc?
Please document what activities you did engage in, how often & for how long?

Type of activity e.g. cleaning, cooking, ironing, gardening etc.	Times per week							Minutes/ Time	Intensity				
	Mon	Tue	Wed	Thur	Fri	Sat	Sun		V. low	Low	Med	High	V. high
CLEANING (2.5)	✓		✓		✓			1 HR	180			✓	
COOKING (2.5)	✓	✓	✓	✓	✓	✓	✓	2 HRS	840		✓		
IRONING (2.3)		✓			✓			1 HRS	120		✓		
GARDENING (5.0)	✓		✓		✓	✓		2 HRS	480	✓			

1620 mins/week of level 2 activity.

4. SEDENTARY ACTIVITIES

4.1 Did you engage in any of the following activities during the daytime between **MONDAY and FRIDAY**?
If so, please indicate below for how many hours per day you performed these activities.

a) Watching TV and videos

(Yes=1)	No=2	Minutes/day from Monday to Friday 3 HRS	(0,9)

180 x5 = 900

b) Reading, drawing, sitting at the computer, sewing, knitting

(Yes=1)	No=2	Minutes/day from Monday to Friday 1 HR	(1,5)

60 x5 = 300

c) Sitting at a desk/lying down

(Yes=1)	No=2	Minutes/day from Monday to Friday 1 HR	(0,9)

60 x5 = 300

@ level 1

4.2 Did you engage in any of the following activities over the weekend (**SAT & SUN**)?
If so, please indicate below for how many hours per day you performed these activities.

a) Watching TV and videos

Yes=1	No=2	Minutes/day during the weekend BREAKS OF 1 HR	120

b) Reading, drawing, sitting at the computer, sewing. Knitting @ level 1

Yes=1	No=2	Minutes/day during the weekend 2 HRS	240

c) Sitting at a desk/lying down

Yes=1	No=2	Minutes /day during the weekend

5. TRANSPORT DURING THE WEEK AND WEEKEND

What form of transport did you use during the week and weekend? You can tick and fill out more than one box.

Car/bus/taxi/train ☐

1,0

How long to get there? 10 minutes

How long to get back? 10 minutes

How many days per week? ONCE OR TWICE

20 mins x 2 = 40 min/week
@ level 1

2,5 Walk ☑

How long to get there? 30 minutes

How long to get back? 30 minutes

How many days per week? TWICE

How fast did you walk? Circle the number:

Slow pace that doesn't change my breathing 1
Slow to medium pace (2)
Medium pace that makes me breathe somewhat harder than normal 3
Medium to fast pace 4
Fast pace that makes me breathe harder than normal 5

60 mins x 2 = 120 min/week
@ level 2 ☐

Walking and taxi, bus or train ☐

There
Walking? 30 minutes

Bus/taxi/train? 10 minutes

Back
Walking? 30 minutes

Bus/taxi/train? 10 minutes

How many days per week? TWICE

How fast did you walk? Circle the number:

Slow pace that doesn't change my breathing 1
Slow to medium pace (2)
Medium pace that makes me breathe somewhat harder than normal 3
Medium to fast pace 4
Fast pace that makes me breathe harder than normal 5

Score: ☐

Bicycle

N/A

How long to get there? _____minutes

How long to get back? _____minutes

How many days per week? _____

How fast did you cycle? Circle the number:

Slow pace that doesn't change my breathing 1
Slow to medium pace 2
Medium pace that makes me breathe somewhat harder than normal 3
Medium to fast pace 4
Fast pace that makes me breathe harder than normal 5

Score: ☐

Other

How long to get there? _____minutes ☐

How long to get back? _____minutes

How many days per week? _____

How fast? Circle the number:

Slow pace that doesn't change my breathing 1
Slow to medium pace 2
Medium pace that makes me breathe somewhat harder than normal 3
Medium to fast pace 4
Fast pace that makes me breathe harder than normal 5

Score: ☐

6. EXTRA MURAL ACTIVITIES IN THE PAST WEEK AND WEEKEND

	Times/week	Hours/time	Intensity scale of 1 – 5 (as above) 1 = no change in breathing 5 = breathe harder than normal
Athletics (track events)			
Athletics (field events)			
Archery			
Badminton			
Ballet			
Basketball			
Cricket			

	Times/week	Hours/time	Intensity scale of 1 – 5. 1 = no change in breathing 5 = breathe harder than normal
Cycling			
Dancing			
Fencing			
Golf			
Gymnastics	2	1 HR	5
Hockey			
Horse riding			
Judo/Karate			
Netball			
Rowing			
Rugby (Touch)			
Rugby (Contact)			
Road running			
Volleyball			
Soccer			
Squash			
Swimming			
Tennis			
Volleyball			
Waterpolo			

4,0 120 mins @ level 3

Other sport	Times/week	Hours/time	Intensity scale of 1 – 5. 1 = no change in breathing 5 = breathe harder than normal

Appendix G

Daily Sleep Diary

Date:_____

- What time did you go to sleep last night? _____h_____
- What time did you wake up this morning? _____h_____
- How long did it take you to fall asleep? _____ (please enter number)

  0 to 30 min = 1

  30 to 60 min = 2

  60 to 90 min = 3

  More than 90 min = 4

- How many times did you wake up last night? _____times
- Was the time you woke up this morning earlier than you wanted?

  Or later than you wanted?

- How many hours did you sleep?_____hours
- Please rate your sleep quality: _____

0 = extremely poor 5 = extremely good

- Please rate your feeling of restfulness: _____

0 = well rested 5 = not at all rested

- How did your sleep last night compare to normal? _____

0 = much worse than usual 5 = much better than usual

Daily sleepiness and fatigue scale:

Awfully sleepy & lack lustre — Marvelously alert and energetic



Morning pain level

No pain — Worst pain ever felt



Evening pain level

No pain — Worst pain ever felt



Appendix H – Activity points for each activity

- Cleaning – 2.5
- Cooking – 2.5
- Gardening – 5.0
- Ironing – 2.3
- Mopping of floors – 2.5
- Washing – 2.0

→ Informal activities

- Watching television/video – 0.9
- Read/sew/knit – 1.5
- Sit in a chair/ lie down – 0.9

→ Sedentary activities

- Taxi – 1.0
- Bus – 1.0
- Walking – 2.5

→ Transport

- Running – 6.0
- Gymnastics – 4.0
- Dancing – 3.0
- Physiotherapy – 4.0

→ Sporting activities

Appendix I

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Miss Daniela Benjamin

CLEARANCE CERTIFICATE	M110633
PROJECT	Does the Short Term use of Stilnox MR Improve both Sleep and Pain Disorders in General Practitioner Patients
INVESTIGATORS	Miss Daniela Benjamin.
DEPARTMENT	School of Physiology
DATE CONSIDERED	24/06/2011
M1106330DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 03/02/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr Alison Bentley

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...