

RAYNAUD'S TREATMENT STUDY
BIOFEEDBACK AUDIOTAPE REVIEW FORM

RTS Form 40
 Rev. 0 10/31/94
 Page 1 of 2

| | | | | |
|-----------|---|---|--|--|
| ID No. | | - | | |
| Form Type | A | R | | |

PART I: IDENTIFICATION

1. Patient's initials:
2. Date of biofeedback session FYB DAYS
 Month Day Year
3. Biofeedback session number: SESSION

PART II: REVIEW OF AUDIOTAPE

4. Type of biofeedback: (1) (2)
 Temperature EMG
5. Was there discussion/mention of the number of Raynaud's attacks? (1) (2)
 Yes No

A. Initiated by: (1) (2)
 Patient Therapist

6. Was there discussion of previous homework? (1) (2)
 Yes No

Check all that apply.

A. PRE-ADAPTATION (1)
 B. ADAPT (1)
 C. BIO (1)
 D. BIO (1)

7. Was there discussion of applied practice? (1) (2)
 Yes No

Skip to Item 9.

8. The applied practice was directed toward (check all that apply):
- A. Places where Raynaud's attacks could occur because of cold APPC (1)
- B. Places where there are stresses other than cold stress APPC (1)
- C. Other circumstances which elicit Raynaud's APPC (1)

9. Reviewer's best estimate of number of therapist's comments:

| | <u>0-2</u> | <u>3-5</u> | <u>5-10</u> | <u>10-20</u> | <u>> 20</u> |
|----------------------|------------|------------|-------------|--------------|--------------------|
| A. Adaptation period | (1) | (2) | (3) | (4) | (5) <i>COMMA</i> |
| B. Baseline period | (1) | (2) | (3) | (4) | (5) <i>COMMA</i> |
| C. Feedback period | (1) | (2) | (3) | (4) | (5) <i>COMMA</i> |

10. The therapist's demeanor was: *(Check all that apply.)*

- A. Professional *Demeanor* (1)
- B. Warm *Demeanor* (1)
- C. Cold *Demeanor* (1)
- D. Not enough conversation to assess demeanor *Demeanor* (1)

11. What scheduled practice was assigned:

- Daily (1) *PRACTICE*
- 2-3 days/week (2)
- 1 day/week (3)
- No practice assigned (4)

12. Did therapist provide additional imagery examples? (1) *EXAMPLE*
 Yes No

13. Were any personal issues of this patient addressed by therapist? (1) *PERISS*
 Yes No

PERISSY

A. If YES, was discussion appropriate and limited? (1) (2)
 Yes No

14. Was any confusion noted about the biofeedback display? (1) *DIS PLAY*
 Yes No

PART III: ADMINISTRATIVE MATTERS

15. Reviewer:

Signature: _____

RTS staff No.: *NEWLERT*

16. Date form completed: _____

Month Day Year

| | | | | |
|-----------|---|---|--|--|
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FORM 40 (Rev. 0)

BIOFEEDBACK AUDIOTAPE REVIEW FORM

| <u>ITEM</u> | <u>NAME</u> | <u>TYPE AND LENGTH</u> | <u>CODES OR UNITS</u> |
|-------------|-------------|------------------------|--|
| HEADER | NEWID | I(4) | Patient ID |
| 2 | F40_DAYS | I(4) | Date of biofeedback session Days from randomization |
| 3 | SESSNBR | I(2) | 1 - 11 |
| 4 | TYPEBIO | I(1) | 1 = Temperature, 2 = EMG |
| 5 | NBRMENT | I(1) | 1 = Yes, 2 = No |
| 5A | INIT | I(1) | 1 = Patient, 2 = Therapist |
| 6 | HOMEWORK | I(1) | 1 = Yes, 2 = No |
| 6A | PREADAPT | } | I(1) |
| 6B | ADAPT | | |
| 6C | BL | | |
| 6D | BIO | | |
| 7 | APPLIED | I(1) | 1 = Yes, 2 = No |
| 8A | APPA | } | I(1) |
| 8B | APPB | | |
| 8C | APPC | | |
| 9A | COMMA | } | I(1) |
| 9B | COMMB | | |
| 9C | COMMC | | |
| | | | |
| | | | 1 = 0 - 2 2 = 3 - 5 3 = 5 - 10 4 = 10 - 20 5 = > 20 |
| 10A | DEMEANA | } | I(1) |
| 10B | DEMEANB | | |
| 10C | DEMEANC | | |
| 10D | DEMEAND | | |
| 11 | PRACTICE | I(1) | 1 = Daily 2 = 2 - 3 days/week 3 = 1 day/week 4 = No practice assigned |
| 12 | EXAMPLE | I(1) | 1 = Yes, 2 = No |
| 13 | PERISS | I(1) | 1 = Yes, 2 = No |
| 13A | PERISSY | I(1) | 1 = Yes, 2 = No |
| 14 | DISPLAY | I(1) | 1 = Yes, 2 = No |
| 15 | NEWCERT | I(3) | RTS staff number Coded 01-22 |

CONTENTS PROCEDURE

| | | | |
|----------------|--------------------------------|-----------------------|-----|
| Data Set Name: | RTS.FORM40 | Observations: | 37 |
| Member Type: | DATA | Variables: | 29 |
| Engine: | V612 | Indexes: | 0 |
| Created: | 11:06 Thursday, April 27, 2000 | Observation Length: | 128 |
| Last Modified: | 11:06 Thursday, April 27, 2000 | Deleted Observations: | 0 |
| Protection: | | Compressed: | NO |
| Data Set Type: | | Sorted: | NO |
| Label: | | | |

-----Engine/Host Dependent Information-----

| | |
|---------------------------|------|
| Data Set Page Size: | 8192 |
| Number of Data Set Pages: | 2 |
| File Format: | 607 |
| First Data Page: | 1 |
| Max Obs per Page: | 63 |
| Obs in First Data Page: | 33 |

-----Alphabetic List of Variables and Attributes-----

| # | Variable | Type | Len | Pos | Format | Informat | Label |
|----|----------|------|-----|-----|--------|----------|--|
| 8 | ADAPT | Num | 4 | 28 | 1. | BEST22. | f40q6b During adaptation period |
| 12 | APPA | Num | 4 | 44 | 1. | BEST22. | f40q8a Places where attacks could occur |
| 13 | APPB | Num | 4 | 48 | 1. | BEST22. | f40q8b Stresses other than cold stress |
| 14 | APPC | Num | 4 | 52 | 1. | BEST22. | f40q8c Other circumstances |
| 11 | APPLIED | Num | 4 | 40 | 1. | BEST22. | f40q7 Discussion of applied practice |
| 10 | BIO | Num | 4 | 36 | 1. | BEST22. | f40q6d During biofeedback period |
| 9 | BL | Num | 4 | 32 | 1. | BEST22. | f40q6c During baseline period |
| 15 | COMMA | Num | 4 | 56 | 1. | BEST22. | f40q9a Comments during adaptation |
| 16 | COMMB | Num | 4 | 60 | 1. | BEST22. | f40q9b Comments during baseline |
| 17 | COMMC | Num | 4 | 64 | 1. | BEST22. | f40q9c Comments during feedback |
| 18 | DEMEANA | Num | 4 | 68 | 1. | BEST22. | f40q10a Therapist was professional |
| 19 | DEMEANB | Num | 4 | 72 | 1. | BEST22. | f40q10b Therapist was warm |
| 20 | DEMEANC | Num | 4 | 76 | 1. | BEST22. | f40q10c Therapist was cold |
| 21 | DEMEAND | Num | 4 | 80 | 1. | BEST22. | f40q10d Not able to assess |
| 26 | DISPLAY | Num | 4 | 100 | 1. | BEST22. | f40q14 Confusion about biofdbk display |
| 23 | EXAMPLE | Num | 4 | 88 | 1. | BEST22. | f40q12 Therapist provided examples |
| 29 | F40_DAYS | Num | 8 | 120 | 4. | | f40q2 Days rand. to biofeedback session |
| 1 | FMYYP | Char | 4 | 0 | | | FMYYP |
| 6 | HOMEWORK | Num | 4 | 20 | 1. | BEST22. | f40q6 Discussion of previous homework |
| 5 | INIT | Num | 4 | 16 | 1. | BEST22. | f40q5a Initiated by (1=patient 2=ther.) |
| 4 | NBRMENT | Num | 4 | 12 | 1. | BEST22. | f40q5 Discussion of Raynauds attacks |
| 28 | NEWCERT | Num | 8 | 112 | 3. | | Reviewer RTS staff number |
| 27 | NEWID | Num | 8 | 104 | 4. | | Patient ID |
| 24 | PERISS | Num | 4 | 92 | 1. | BEST22. | f40q13 Personal issues addressed |
| 25 | PERISSY | Num | 4 | 96 | 1. | BEST22. | f40q13a Appropriate & limited discussion |
| 22 | PRACTICE | Num | 4 | 84 | 1. | BEST22. | f40q11 Practice assigned |
| 7 | PREADAPT | Num | 4 | 24 | 1. | BEST22. | f40q6a During pre-adaptation period |
| 2 | SESSNBR | Num | 4 | 4 | 2. | BEST22. | f40q3 Biofeedback session number |
| 3 | TYPEBIO | Num | 4 | 8 | 1. | BEST22. | f40q4 Type of biofeedback (1=temp 2=emg) |

| Variable | Label | N | Mean | Std Dev | Minimum | Maximum |
|----------|--|----|-------|---------|---------|---------|
| SESSNBR | f40q3 Biofeedback session number | 37 | 6.5 | 3.1 | 1.0 | 11.0 |
| TYPEBIO | f40q4 Type of biofeedback (1=temp 2=eng) | 36 | 1.6 | 0.5 | 1.0 | 2.0 |
| NBRMENT | f40q5 Discussion of Raynauds attacks | 36 | 1.9 | 0.4 | 1.0 | 2.0 |
| INIT | f40q5a Initiated by (1=patient 2=ther.) | 5 | 1.2 | 0.4 | 1.0 | 2.0 |
| HOMEWORK | f40q6 Discussion of previous homework | 36 | 1.1 | 0.2 | 1.0 | 2.0 |
| PREADAPT | f40q6a During pre-adaptation period | 34 | 1.4 | 0.5 | 1.0 | 2.0 |
| ADAPT | f40q6b During adaptation period | 34 | 1.7 | 0.4 | 1.0 | 2.0 |
| BL | f40q6c During baseline period | 34 | 2.0 | 0.0 | 2.0 | 2.0 |
| BIO | f40q6d During biofeedback period | 34 | 2.0 | 0.0 | 2.0 | 2.0 |
| APPLIED | f40q7 Discussion of applied practice | 36 | 1.3 | 0.5 | 1.0 | 2.0 |
| APPA | f40q8a Places where attacks could occur | 25 | 1.2 | 0.4 | 1.0 | 2.0 |
| APPB | f40q8b Stresses other than cold stress | 25 | 1.7 | 0.5 | 1.0 | 2.0 |
| APPC | f40q8c Other circumstances | 24 | 1.7 | 0.5 | 1.0 | 2.0 |
| COMMA | f40q9a Comments during adaptation | 33 | 1.3 | 0.9 | 1.0 | 5.0 |
| COMMB | f40q9b Comments during baseline | 33 | 1.0 | 0.0 | 1.0 | 1.0 |
| COMMC | f40q9c Comments during feedback | 33 | 1.1 | 0.3 | 1.0 | 3.0 |
| DEMEANA | f40q10a Therapist was professional | 37 | 1.4 | 0.5 | 1.0 | 2.0 |
| DEMEANB | f40q10b Therapist was warm | 37 | 1.2 | 0.4 | 1.0 | 2.0 |
| DEMEANC | f40q10c Therapist was cold | 37 | 2.0 | 0.0 | 2.0 | 2.0 |
| DEMEAND | f40q10d Not able to assess | 37 | 2.0 | 0.0 | 2.0 | 2.0 |
| PRACTICE | f40q11 Practice assigned | 32 | 1.4 | 1.0 | 1.0 | 4.0 |
| EXAMPLE | f40q12 Therapist provided examples | 35 | 1.9 | 0.2 | 1.0 | 2.0 |
| PERISS | f40q13 Personal issues addressed | 35 | 1.8 | 0.4 | 1.0 | 2.0 |
| PERISSY | f40q13a Appropriate & limited discussion | 10 | 1.1 | 0.3 | 1.0 | 2.0 |
| DISPLAY | f40q14 Confusion about biofdbk display | 35 | 2.0 | 0.0 | 2.0 | 2.0 |
| NEWID | Patient ID | 37 | 158.3 | 90.8 | 10.0 | 296.0 |
| NEWCERT | Reviewer RTS staff number | 37 | 11.2 | 5.0 | 1.0 | 22.0 |
| F40_DAYS | f40q2 Days rand. to biofeedback session | 37 | 34.2 | 22.6 | 1.0 | 108.0 |

FMYYP

| FMYYP | Frequency | Percent | Cumulative Frequency | Cumulative Percent |
|-------|-----------|---------|-------------------------|-----------------------|
| AR01 | 26 | 70.3 | 26 | 70.3 |
| AR02 | 10 | 27.0 | 36 | 97.3 |
| AR03 | 1 | 2.7 | 37 | 100.0 |